FOOD AND DRUG ADMINISTRATION (FDA)

CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

FEMALE SEXUAL DYSFUNCTION

PATIENT-FOCUSED DRUG DEVELOPMENT

PUBLIC MEETING

Monday, October 27, 2014

FDA White Oak Campus

10903 New Hampshire Avenue

Bldg. 31, The Great Room

Silver Spring, Maryland 20993

Reported by: Michael Farkas

Capital Reporting Company

M E E T I N G R O S T E R

FDA PANEL

Julie Beitz

Hylton Joffe

Audrey Gassman, M.D.

Christina Chang, M.D., M.P.H.

Marcea Whitaker

Theresa Mullin, Ph.D.

Ashley Slagle

Sandra Kweder, M.D.

T A B L E O F C O N T E N T S

P R O C E E D I N G S

OPENING REMARKS

DR. EGGERS: One minute to still say good morning and then it will be afternoon. We are going to get started in a minute. So if you want to take your seats. I see actually everyone is all prepared for this. This is the quickest we've ever gotten silent for one of these meetings before. So I think we'll begin.

Good afternoon. My name is Sara Eggers and I'm in CDER, the Center for Drug Evaluation and Research in the Office of Strategic Programs.

I'd like to welcome you to today's meeting on Female Sexual Dysfunction particularly related to interest and arousal as part of our agency's patient- focused drug development initiative.

[Applause.]

Thank you. We -- give me one second. I can do this on my own without any notes.

We have a very full day today and tomorrow. And we have a lot of work to do on all

of our parts. So I'm going to soon turn it over to Dr. Audrey Gassman who will give a proper welcome. But before we do I want to go over a few agenda items and other details.

Oh, they we go. Okay. We're going to start with FDA doing some talking first to set the context by giving an overview of our patient-focused drug development initiative, giving some background on female sexual dysfunction and its therapeutic options. And then I'll come back and give an overview of the discussion format. I will be serving as the facilitator today.

Our two primary topics are: number one the disease symptoms and daily impacts that matter most to patients. What is it about their condition that bothers them the most; that bothers you the most? And then topic two, what are your perspectives on current approaches to treating female sexual dysfunction particularly as it relates to interest and arousal.

Those are our two main discussion topics today. We will engage patients and patient

representatives in the audience participating here today and on the Web.

And then as we do for all of our patient- focused drug development meetings, we have a half hour for an open public comment at the end of the meeting which will give anyone a chance to make a comment even if it is not quite related to the topics at hand. I believe the registration for that has been -- we have filled to capacity for that open public comment and Pujita will be giving you more information then.

And then at the end we will wrap up and do closing remarks for today. And then tomorrow is our more scientific discussion on specific issues related to drug development and evaluation for FSD particularly interest and arousal.

There are a few housekeeping issues. The restrooms are located about as far away as you can go at the end of the hall that way. There is a Kiosk that has basic food and we encourage you to get up as you need. This is not a formal meeting setting. So if you need to get up to use

the restrooms, please do. Please silence your phones.

We will be recording the transcript of this meeting. We are also on the Webcast. So a shout out to those of you on the Webcast, we understand there is a very healthy participation registration for the Webcast. It is great to see so much interest in this meeting. So our Webcast will be live right now and it will also be archived on our Web site.

We also understand that there are media outlets present. You probably noticed them on your way in. And we are happy to see the level of excitement and interest in this meeting. We just want to make you aware that their presence is in no way affiliated with FDA. And your participation or your non-participation in any kind of -- if they ask you to participate in an interview, is completely at your discretion. Okay.

With that I'm going to turn it to Audrey who will give some welcome remarks.

Thank you.

DR. GASSMAN: Thank you, Sara.

Good afternoon and welcome to today's meeting on Female Sexual Dysfunction Patient-Focused Drug Development. I'm Audrey Gassman, Deputy Director of the Division of Bone, Reproductive and Urologic Products, also known as DBRUP in the Office of New Drugs at the FDA.

This is an important meeting and we are looking forward to hearing from women who experience sexual dysfunction and what they look for in treatments for this condition. We're pleased to see so many patients and advocates in the audience. And I understand that there are many others joining remotely from the Web. Thank you again for being here and being part of this meeting.

Today's meeting is one in a series of what is called patient FDA's Patient-Focused Drug Development meetings. Theresa Mullin will describe this initiative in more detail in a few minutes.

Female sexual dysfunction is a complex and multi-faceted disorder that affects women across a wide spectrum of symptoms and severity. Our meeting over the next two days will focus on the most common form female sexual interest and arousal disorder also known as FSIAD.

Later Christina Chang, our lead medical team leader, will provide some brief background on FSIAD.

I just want to say that we recognize that this is a condition that can greatly impact the quality of life.

The FDA is committed to supporting the development of drug therapies for FSD. When we discuss drug development over the next two days we are referring to the process of identifying, developing and evaluating potential therapies that can help patients manage their FSD. FDA's mission is to protect and promote public health by evaluating the safety and efficacy of new drugs.

While we play a critical role in drug development, we are just one part of the process.

We do not develop drugs or conduct clinical trials.

Drug companies often working with researchers or patient communities are the ones who will conduct the trials and submit applications for new drugs to the FDA. We work closely with the drug companies throughout the drug development process. We are therefore glad to see representation and tremendous interest in today's meeting from industry, academia and other government partners in the room and on the Web.

I want to spend a few minutes providing a bit of background on the FDA's important role in drug evaluation. For a drug to be approved for marketing FDA must determine that it is safe and effective for its intended use. Our regulatory decisions are based on science, medicine as well as legal and regulatory standards. First and foremost the drug must demonstrate substantial evidence of efficacy for its intended use. This is a requirement by law.

Although the meaning of safe is not

explicitly defined in the statutes or regulations, the safety of a drug is assessed by determining whether the benefits outweigh the risks. The FDA makes each determination for a new drug based on the totality of information provided by drug companies in their new drug application which is a request for marketing authorization in the U.S.

FDA's benefit risk assessment takes into account many factors including the presence of alternative therapies for the indication, the goals of the proposed therapy, the magnitude of the demonstrated benefit, and the nature of the risks associated with the new product.

We take our roles very seriously. We are aware of claims from external sources that the FDA favors therapies in regard to men when it comes to indications related to sexual dysfunction or sexual difficulties. As a representative of the Division and of the FDA I want to assure you that we are willing and ready to work with all sponsors and investigators to address these conditions whether they are in men, women, or

both.

We evaluate all applications individually based on submitted evidence and do not apply different standards or regulatory standards when making our decisions.

Drug development for a female sexual dysfunction is very complicated due to many factors such as the ability to diagnose the dysfunction, the presence of underlying medical conditions that may be responsible for the dysfunction, challenges identifying outcomes that are both meaningful to patients and are measurable, and challenges designing trials that can reliably assess drug efficacy and safety.

FDA wants to help facilitate this complicated process. For example, we advise all sponsors who intend to treat symptom related conditions including female sexual dysfunction to consider our 2009 guidance on development of patient- reported outcomes which provides recommendations for development.

There are still many scientific issues

that need to be resolved in this field. Tomorrow we will have a discussion that will be more technical in nature exploring important aspects of drug development process for FSD. We will cover topics that include diagnostic criteria, clinical trial design and outcome measures.

Today's meeting, however, is about listening to patients. We think very carefully about the kinds of things we should be measuring and evaluating for new drug for FSD and hearing your perspectives on this will be invaluable. Specifically we would like to hear from patients what symptoms matter most and how they affect daily life and sexual experiences. We are also interested in understanding what patients are currently doing to help themselves to treat this condition.

What we hear from you today can help us understand what patients would value in treatments for FSD. Your input can help us understand how to develop better end points to measure the aspects of FSD that are important to patients and to

develop better tools such as patient-reported outcomes or PROs.

Sara Eggers will explain our meeting format process which is designed to encourage a rich discussion today.

I want to reiterate one point. The important issues that I have mentioned are common to the development and evaluation for any drug to treat female sexual dysfunction. Therefore, our goal today and tomorrow for that matter is to explore these issues broadly and not focus attention on any one specific drug or therapy.

Thank you again for your participation and for being here today.

I'll now turn it over to Theresa Mullin who will provide some background on FDA's overall patient- focused drug development efforts.

DR. MULLIN: Hi. Theresa Mullin and I direct the Office of Strategic Programs in the Center for Drugs. And I just want to take a minute to give you the background on this meeting and it is one -- one way we look at this is one of

a series of meetings that we are I'll say piloting this approach to do a better job of more systematically trying to collect information from patients about their perspective on their condition and the treatments available as Andrea mentioned.

We understand that the patient's perspective is quite critical to our understanding and thus our ability to assess the benefits and risks of any new therapy. Patients are the ones who experience the disease; they are the ones who will get any benefit that can be gotten from a new drug; and also be the ones to experience the risks. And so their role is quite critical and unique in terms of informing our decision making.

And before this initiative began in 2012 we didn't really have a way to systematically collect this kind of information. We had a patient representative program that allowed us to involve one or two patients in our process. And, of course, because they would be involved in the discussion of particular drugs we had to go

through a lot of conflict of interest screening. And we still have this program and it is very valuable. But as you can hear it limits our ability to get wider input. And we knew we really needed to hear from as diverse and broad a community as possible who is affected by any given disease.

So we designed this program and included it in our reauthorized prescription drug user fee commitments that we made in 2012 and so we have committed in that program to include at least 20 meetings in different disease areas over the five years to sort of as I said pilot this approach and figure out how we can optimize it to get the most benefit both in the meeting and then in our follow up to these meetings. This helps us better understand and advise sponsors during the drug development process and also, of course, also give us more insight than we would have had in reviewing any particular application that gets submitted.

So -- just a minute, I need to find the

advance key. Ah. Okay. Did I already -- did I go twice? I'm sorry; my slides look so much alike that - - oh there we go.

So this process just quickly started in 2012. We published a Federal Register Notice which is our usual way of communicating to the public with about 40 diseases in it. We asked for comment. We got about 4,500 comments on that list. And that helped us to sort of sort through. We came up with a list of 16 that we are focusing on in the first three years.

And then in this slide as you see there is a Federal Register Notice there on October the 8th we published a list of diseases that we were offering as candidates for the final two years of the program, 2016 and '17 and we're hoping to receive public comment by I think December the 5th on what we will set up there.

And this slide shows you the diseases that we are covering in those first three years. The ones on the left for fiscal year '13 and '14 are ones we've already done at this point. And we

are working our way through producing our reports and following up on those.

And today's meeting is on female sexual dysfunction. It is the first meeting we are having in 2015 for this fiscal year.

And so as Andrea said each of our meetings covers two essential areas which are: What are the patients' experiences with the disease? What are the most problematic aspects of it? What are they doing to treat it today? What are they -- there may not be any good treatments available but what are they doing to try to cope with the condition?

We start with those questions and we tailor it further. The review division may have other things they want to take advantage of having you here today to hear about other things as well. So for example we had a meeting on HIV Aids, we took that opportunity to talk to the patients about their perspective on cure research. Would they be willing to forego the treatments that were available to participate in a trial that involved

cure therapy? And so there are things we can talk to the patients or hear from them about that provide a unique opportunity. We try to put those into these meetings as well if we can.

And then we take what we learn here; what we have found is the more active participation, the more we get to hear from what you think and the more patients who are able to participate here in the room or on the Webcast or through the Docket, the more we benefit and the more of a rich source of information this gives us.

So we are very happy, gratified to have so many people here today.

And so the final slide I have here is the report that we produce at the end of this which is sort of our first deliverable, our first product of these meetings is called the voice of the patient. So following each of these meetings we try to take the transcript and the other information, our notes and write up the summary of what we heard and try to capture it in the words

that you used to tell us what you are experiencing because those are really the most authentic way we can record this and try to convey to the reviewers today or beyond this what we heard and what you're experiencing.

We take that report and use it as a way to communicate in the future to our staff, to have it as a reference document, and also to inform our subsequent efforts that we may try to segue from this into patient-reported outcome tools and other ways to follow up longer term to give the full benefit of this for future drug development in our decision making.

And with that I'll turn it over to the next speaker.

DR. CHANG: Thank you, Dr. Mullin. Good afternoon everyone. Welcome to the Patient-Focused Drug Development meeting on female sexual interest/arousal disorder here at FDA.

My name is Christina Chang. I am a clinical team leader in the Division of Bone, Reproductive and Urologic Products here in CDER.

And my division reviews the drugs that intended to treat female sexual dysfunction or FSD for short.

My team is specifically responsible for reviewing any clinical data that are submitted in support of these applications.

We appreciate so many of you being here participating in this workshop here on campus. And also for those who are joining us via the Web. And we are very grateful to those patients who are willing to share the personal stories on a very, very sensitive topic. So again very welcome.

And given the limited time that we have and the complexity of the female sexual dysfunction overall we would like to focus today's workshop primarily on FSIAD or female sexual interest arousal disorder.

The reason for today's meeting is that although sexual dysfunction is not a life threatening condition we do realize and recognize that the dysfunction can significantly impact a woman's quality of life. And its affects can definitely result in major disturbances in family

life. Service studies have suggested that women more than men have complained about having sexual difficulties and that these problems appear to be very common in U.S. women. In this frequently cited 1995 study women between the ages of 18 and 59 reported complaints to the investigators and these complaints include lack of sexual desire, difficulty in becoming aroused, inability to achieve orgasm, anxiety about sexual performance, reaching orgasm too rapidly, pain during sexual intercourse, or failure to derive pleasure from sex.

The 43 percent figure emerged from analysis of responses from more the 1700 women. Some critics have pointed out that the women in the study were not specifically asked about whether their complaints were severe enough to bother them. And subsequently a lot of discussions ensued on how we should define what exactly constitutes female sexual dysfunction.

But it is not possible to talk about dysfunction without first discussing normal sexual

function. Normal sexual response in women depends on a very complex web of interacting factors including physiological, emotional, relationship dynamics, and much, much more. Significant changes in any of these components can affect a woman's sexual desire, response and satisfaction.

Although the definition of sexual dysfunction in women has been the subject of some debate because it appears to be less quantifiable what has not been disputed is that for a woman to be diagnosed with a dysfunction her symptoms must be severe enough to be a source of personal distress. And as a 2008 study by Dr. Shifren (ph) shows that an estimated 12 percent of U.S. adult women may have sexual problems when their diagnosis takes into account the presence of personal distress.

So we went from 43 percent to 12 percent but this is obviously still a significant segment of the female population in this country.

I want to move on now to a brief overview of the female sexual dysfunction as

defined by the

American Psychiatric Association. FSD is a term that covers a heterogeneous collection of conditions and in the past FSD was classified into four different conditions. The first: Hypoactive sexual desire disorder characterized by the absence or reduced interest in sexual activity as well as not being receptive to a partner's initiation of sexual activity. Second: Female sexual arousal disorder characterized by the inability to attain or maintain sexual excitement. Third: Orgasmic disorder characterized by the difficulty to attain orgasm despite sufficient arousal. And the last being pain disorder where women complain of pain during sexual intercourse.

In May of last year Hypoactive Sexual Desire Disorder or HSDD and Female Sexual Arousal Disorder or FSAD were combined into a single diagnosis in the Fifth Edition of the Diagnostic and Statistical Manual. The other disorders remain relatively unchanged.

With FSIAD being a relatively new

diagnosis we know that there has been limited clinical experience and consequently we are hoping very much to hear your thoughts on this new diagnosis.

As outlined in the DSM5 here are the features that are used to arrive at a diagnosis of FSIAD. There are six symptoms that I have taken verbatim from the diagnostic manual and as you can see the first three as well as the fifth symptom relate to the absent or reduced sexual desire. The final three symptoms have to do with the absent or reduced arousal.

The manual specifies that to qualify for the diagnosis the patient must have had at least three of these symptoms for at least six months in duration. And specifically for two of the symptoms namely number four and number six the manual also mandates documenting the frequency when the patient would notice these symptoms. So the patients report these two symptoms, number four and number six, occurring in at least 75 percent of the sexual encounters.

Furthermore the symptoms in the previous slide must cause significant distress to the patient.

However, what clinically significant distress means exactly is not really defined in the manual. And most importantly three other contributors to sexual dysfunction must be ruled out before making the diagnosis. First: the problem with having either low desire or low arousal cannot be explained by another psychiatric disorder such as depression or anxiety.

Second: any relationship factors should be considered before making a diagnosis. But here again the manual does not elaborate on what these relationship stressors may be or how severe they have to be. It seems that there are many other stressors besides partner violence such as kids, work, other relationship dynamics, et cetera. So we would like to hear your perspective. And finally the third factor that needs to be considered is: medical illnesses, medications or any other substance use. So FSIAD is really

almost a diagnosis of exclusion.

Additionally the manual outlines other ways to describe FSIAD such as using a severity grading, classified as mild, moderate, or severe. Another way of categorizing the condition is whether the patient has always had the condition or it's something new in her sexual experience. The third classification would be whether the condition is situational such that it only happens in specific environments with a particular partner or whether the conditions is generalized meaning that there are no identifiable triggers.

And as we all know there are no drugs approved by FDA to specifically treat FSIAD, HSDD, or FSAD. Some existing products have been studied for these conditions. But these products have had their own issues. For example Sildenafil or Viagra was studied for the treatment of female sexual arousal dysfunction or disorder but was not shown to be effective.

Other products such as hormonal therapies may have potential safety issues when

they are taken long term.

Non drug therapies include behavioral therapies or couples sex therapy. But we are not aware of any large scale studies to support these treatments.

So we are very interested in hearing from the patients as to what remedies you've been using to help with your sexual problems and whether you feel that they've helped or not.

I also want to point out that for pain associated with sex or the sexual pain disorder FDA has actually approved several products. In addition to several estrogen containing products, we've recently approves Ospemifene for the treatment of pain during intercourse that is associated with vulvar or vaginal changes due to menopause.

So part of the rationale for convening this meeting today is our recognition that we do not yet have drug therapies to help women with either low sexual desire or low arousal.

And as I mentioned already when it comes

to HSDD, FSAD, or FSIAD making the diagnosis correctly is complicated. Accordingly developing drugs to treat these conditions is also very complicated. And this workshop presents an opportunity that going forward the FDA industry and the larger community could be hopefully on the same page with respect to the terminologies relating to these conditions. And identifying the appropriate patients which really have dysfunction in desire or arousal can help us move forward in developing safe and effective drug therapies for those who can really benefit.

From the discussion today we'd also like to get a better sense from the patients on what are the most important symptoms we should measure in clinical trials to see if a drug can be a benefit. And how shall we measure these changes. These are very important parameters in assessing whether a drug works for its intended purpose.

In order to help identify meaningful end points for clinical trials the FDA is very interested in patient-reported outcomes. Patient-

reported outcomes or PROs can represent direct measures of treatment benefit in identifying how a patient feels or how a patient functions.

For conditions like FSIAD, HSDD, or FSAD where a diagnosis is based on a more qualitative than quantitative assessment input from the patients is really essential. And we very much would like to see well defined and reliable PRO instruments developed, validated, and evaluated in clinical trials for drug development.

I will just put in a plug for tomorrow's program. We are also having a scientific workshop tomorrow to discuss some of the very challenging issues in developing drug therapies for these conditions and we hope that many of you will be able to join us tomorrow.

Thank you all again for being here. And now let me turn it over to Dr. Sara Eggers.

DR. EGGERS: Thank you very much to all of the FDA colleagues for providing that background. We've got one more FDA speaker that stands in the way of the discussion with you, so

I'll try to make this as brief as possible.

This meeting today is quite different in format and style from other public meetings you may have attended. And as Audrey mentioned that is really the goal; that is our intent is to have a format that really encourages and enables dialogue with patients.

The two topics that we are covering we've mentioned this before but I'll go into a bit more detail. One the symptoms that matter most to you and in particular symptoms or aspects of your condition that have the most significant impact on your sexual experience, specifically and more broadly on your daily life. And how specifically do these symptoms affect your sexual experiences. And how, if at all, do they change over time?

And then after the break we'll come back and talk about the approaches to treating FSIAD. What are you currently doing to treat your condition and its symptoms? How well do they work for your? What are their biggest downsides? And importantly what would you look for in an ideal

treatment? What specific things would you like -- aspects of your condition would you like to see addressed?

As far as our format for each of those two topics we're first going to ask a panel of patients to share their stories with us and provide a good foundation for a facilitated discussion that will follow.

And those of you who are on Topic 1 if you could please make your way to the front at this time. Bring your name tags. If you don't have tent card, I probably have it up here for you.

These panel members were identified from those when we put out the invitation in the Federal Register Notice we invited people to submit comments if they were interested in presenting comments to start our discussion and we identified women who experience a range of symptoms, a reflective range of perspectives to attend. So I thank you in advance for coming up here.

After they have their comments, there may be some clarifying questions. But then we are going to move out into the facilitated discussion, really follow up and build on what we heard from the panel discussants and ask more detailed questions for that.

And the purpose here is to build on what we heard from the panel and really get a sense of what is more in depth and what range of perspectives and experiences are out there.

So, we have staff floating around; you don't have to get up to any microphones. We have staff floating around who will bring the mic to you. So when I ask a question, just raise your hand and we're going to try to take everyone who wants to speak. I have some ground rules that we will go over in a minute.

We are going to ask that you please state your first name. We don't need your last name. Just your first name is fine before speaking. And for the sake of transparency we also request that at the time that you first speak

and that includes the panel discussants as well that you disclose if you are affiliated with an organization that has an interest in FSD or if your travel has been sponsored or if you have significant financial interest in FSD drug development. That is in the sake of transparency and we'll just ask everyone to disclose that at the first time that they speak.

And when we ask a question try to keep your responses focused on the specific question or topic at hand. You should have a chance to speak on any topics as they come up. So that will really help the conversation move forward. Please try to keep those responses limited to a minute or two.

I'm going to regularly ask through a show of hands if you in the audience and the Webcast can chime in as well, if you generally share a particular view that was just experiences so that we can really build on what one another is saying.

So we also have a strong Web

participation. And this is really important. We want to hear from the women on the Web today as well. Although we may not read or summarize all of your comments today they are being reviewed, they will be part of the public record and we are incorporating them into our final reports.

We are also going to occasionally go to the phones to give you on the Web another opportunity to contribute as time permits. All of you will have a chance to answer polling questions and I am going to ask for the polling questions, we will put them on the table please, there are little clickers, okay so there are going to be some clickers floating around and we are going to ask that just women who identify themselves as having FSD and particular interest in arousal to take the clicker and to answer the questions.

This is not at all a scientific survey. It is merely a discussion aid. It helps us understand who is in the room and what perspectives you might share and what your experiences might be. So please don't treat this

in any way as a scientific exercise.

But we do find that it really does enable a discussion. We can build on things that we hear from the polling.

We also importantly have a Public Docket. We know that there are many, many issues that you won't be able to talk about today and many things that you wish you could talk about in more detail and you all have the opportunity, anyone in the audience, anyone participating in the meeting whether you are a patient, patient representative or not to contribute a comment, follow up on what you have said at the meeting or a comment that just provides your full story. And if you have people who weren't able to attend the meeting today we encourage them as well to share their stories with us and your experiences.

On our Website you can see the information for the Public Docket. A Docket is an unfortunate word for a repository that you can -- it is a vehicle for us to get comments from the public. So it is just a Website you are sending

your comment to. When you go to Regulations.gov if you follow our Web link you will get to a link and just click on the comment now button.

There are other resources for you so the FDA's office of Health and Constituent Affairs really focuses on providing patients with information that they need. And they are the ones as Theresa mentioned run the patient representative program. So if you have any questions or you would like to follow up with them, their information is here.

And also CDER now has a new Office of Professional Affairs and Stakeholder Engagement. And we have Ria Blakely (ph) is around; she is right there in the back, has her hand raised. Particularly if you are an organization or a health care provider or others who wants to engage with FDA you may feel free to reach out to Ria.

Our primary goal today is to enable a fair and open discussion. To insure that I'd like to go over a few participation ground rules. We are here first and foremost to listen to women who

experience female sexual dysfunction particularly as it relates to interest and arousal. So we encourage all participants with FSAID to contribute to the dialogue. Your partners and advocates are welcome, too, but we ask that you focus your participation on helping further understand women's experiences and perspectives with respect to the questions posed. We are going to try to accommodate everyone who wants to speak and again if we don't get your full comments, please go to the Docket.

For the advocate organizations and the many, many health care providers that have registered today we encourage you to listen to the dialogue today and submit a comment to the Docket that expresses your understanding as to the dialogue which the input that we hear today reflects your understanding of the women that you work with, reflects their perspective and experiences because we do want to make sure that we do reflect the broad range of experiences that are out there and perspectives that are out there.

We are happy to see participants today who represent research, industry and other organizations. We do believe that this input is important for you as well and we just ask you to stay in listening mode today.

FDA staff is here to listen and to take notes and to help ask follow up questions as the day goes forward. We won't be able to address any questions from the audience today that might arise.

The purpose of tomorrow's meeting is to discuss these issues, regulatory and drug development issues in more depth. So if you have a question and you are able to participate tomorrow, I recommend that you hold it, see if it gets answered there and there is Q&A sessions and there are opportunities to ask those questions. And if at the end of that time you still haven't heard the answers that you are looking for, please the contact information for Ria and for the Office of Health and Constituent Affairs or there are evaluation forms at the end of today's meeting

that we are going to ask you to fill out, feel free to write your questions and we will try to address them in some way either directly or indirectly.

As we described today our discussion is focused on symptoms first and foremost and on experiences with treatment and approaches. We understand that there are other important issues, many other important issues to insure that the women with FSD get treatment and support that they need. Our narrow focus today reflects FDA's need for specific information as both Audrey and Christina mentioned.

There are a few things that our discussion will not focus on today. And that includes specific issues with any particular product or any particular drug under evaluation.

We are also not addressing the broader question about whether there is or is not a need for medical treatment for FSD. As Dr. Gassman stated FDA is committing to supporting the development of drug therapies for FSD. And our

discussion may touch upon specific treatments and this is appropriate. We do want to ask about treatments. However, the discussion of those treatments we hope is done in a way that helps us understand those broader issues. What symptoms are generally being addressed? How do you know that that treatment is working? We don't really necessarily care what treatment it is, what is useful to us is to say well, how does a woman know when a treatment is working? What specific things it is addressing? And how meaningful is that to you as patients?

The opinions expressed here today are personal opinions. This discussion is going to touch on very sensitive topics. I don't even need to say that. We all know that this is a very, very personal experience that all women are facing, sexual experience. Everyone faces these as very personal experiences. And we want the women up here to feel comfortable talking about their experiences and expressing their perspectives. Therefore, demonstrating respect is

of paramount importance. We expect everyone here to be on that same page in terms of respect.

Please wait to be acknowledged before speaking and then speak into the microphone. And please do not direct your comment to or about any specific individual and avoid negative language and please keep side conversations to a minimum.

Okay. Got that over with.

Now let's move on. We want your feedback to the meeting, we really do appreciate the evaluations that we get and we do review them carefully. We have another several meetings moving forward and what we learn from each of these meetings really helps us with the next.

Does everyone have a clicker who wants a clicker? We have a few of the polling questions and these just again give us a sense of who is in the room and who is on the Web at this point. So we start with an easy one. This will help you practice with the clickers as well.

So where do you live, where are you coming from; a) if you are inside the Washington,

D.C. metro area and b) if you are from outside?

As we expected this is an issue that has a very wide geographic representation here today so we thank you. We thank you all whether you traversed the beltway everyday and so this is something you routinely do or if this is one of the rare occasions when you have to do so.

Are you participating today because you personally are significantly bothered by: a) absent or reduced desire for interest in sexual activity or sexual fantasies; b) absent or reduced sexual excitement, sexual pleasure or sexual arousal during sexual activity; c) both; d) neither but you have some other symptom associated with FSD? And if none of these apply, just don't answer the question.

We'll give some time.

Okay. So a lot of you here are battling with both of these. We will delve into these, try to tease them apart a bit and for those of you that feel that only one or the other, we will try to get your experiences on how you experience the

one but not the other and how those experiences are for you.

What is your age?

We have a range of ages represented here. It is really wonderful to see so many people who are younger than 30 here participating today as well as the entire range. This differing of the age range indicates that you might have experiences that are very different depending on whether you have or have not gone through menopause.

Can I back up a minute? I neglected to ask about the Web polling results for the previous question about what their interest is in this meeting.

MS. GIAMBONE: Yes, we have about 55 percent of the people on line voted for absent or reduced desire or interest in sexual activity or sexual fantasies. And for question 3 we have for the age we have about one third of the people between the ages of 31 to 40 and about 30 percent of the people between 51 and 60.

DR. EGGERS: Okay. Thank you.

Have you received a diagnosis of Female Sexual Interest or Arousal Disorder, FSIAD, Hypoactive Sexual Desire Disorder, HSDD, or Female Sexual Arousal Disorder, FSAD from a health care provider?

Okay. So it looks like we have a mix of both.

From here on I get tongue-tied very easily so I am going to just say FSD from now on and by that we mean FSD with particular focus on interest and arousal. But if I have to say either the acronyms out we could be here until tomorrow.

How long have you had symptoms of FSD? Less than five years, five to ten, ten to 20, more than 20, or you are not sure.

Okay. This is also a very nice mix of experiences that we have here. We are going to try to tease apart some of that a little bit as we go on.

And on the Web?

MS. GIAMBONE: 50 percent of the people

on the Web said that they have had symptoms from five to ten years.

DR. EGGERS: Okay. That is it for our polling questions for now. And we have a few more as the two discussion topics unfold. But thank you very much for answering those.

And now it is time to move into the Topic 1 discussion. And again this is on -- and everyone you have the agenda and the questions that we posed in our Federal Register Notice that were the focus of today's discussion are printed on the last page or the back of that agenda. This is very much just a summary of those to fit on one slide. But we've gone over what the main point of this discussion is.

A few other things we want to know is about if your symptoms wax and wane over time. We have a few questions about if you are asked to rate your symptoms. We have some considerations we'd like to get from you. And then finally we'll talk about what worries you about that distress portion as we get into the facilitated discussion.

But to kick it off we are going to have each of the four of you go. I know you all by phone, by name, but I don't -- they should have printed your names on the other sides of the

VICTORIA: Do you want me to start?

DR. EGGERS: You can start. Oh and when you -- just push it once.

VICTORIA: Hello. Okay. My name is Viki and I have to say at first Veritas has taking care of my travel expenses through grants from Sprout Pharmaceuticals, Even the Score, and the Institute for Sexual Medicine.

So starting off I'm 39 years old. I'm here to tell my story about my experience living with HSDD. My symptoms became significantly noticeable about five years ago after the birth of my fourth child. A couple years before that I had experienced a slight decrease in desire and fewer sexual occurrences but I figure it was just because we were both busier in our lives.

I realized that there was something more going on with me when I started to just not want

to have sex at all. I stopped initiating sex and my desire became nonexistent. This was not normal for me. My husband and I had a very fulfilling and healthy sex life up until this point. Our friends would even make comments about how we couldn't keep our hands off each other.

I sought out answers from different specialists to find out what was happening to me and if there was something I could do. I had an array of tests done spanning from full panel blood work to hormone testing to even internal ultrasounds. No one had any answers for me when all of my tests came back normal. But I knew there had to be something else going on.

My mom told me I should go to San Diego to see Dr. Goldstein because she was a patient of his and he may have answers for me. I was reluctant at first because I had already spent so much money on testing and my insurance would not cover any test that had to do with hormones. My mom felt it was so important for me to see him that she flew me to San Diego and he diagnosed me

with HSDD.

My symptoms rapidly worsened over the last three years. I found myself avoiding any situations where a sexual experience may occur. For example going to bed after my husband fell asleep or jumping out of bed in the morning before -- sorry, before he got up just so he wouldn't try to initiate sex. I even found myself avoiding simple hugs and kisses.

The defining moment for me was when my husband and I took a vacation for a week to Mexico without kids. This was supposed to be a time for the two of us to relax and enjoy each other. In the past when we had taken vacations together we barely left the room. My mom always joked "don't get pregnant" when we left. But unfortunately my symptoms stayed the same. In a beautiful place with the man I love my body was like a shell with nothing inside. I just did not feel like I wanted to have sex. My desire was still gone. This was devastating to both of us and definitely put a strain on the trip.

My sexual experiences recently are more out of obligation to keep my husband satisfied after all it is not his fault this is happening to me.

I feel it is important to say my husband and I talk very openly about HSDD. I know he loves me very much and tries hard to understand. He does not have any problems as far as his sexual function or desire. So it is difficult for him to relate.

I would like to note if he did have a problem with sexual dysfunction as a man he would have many options for treatment. But that being said it has put a big strain on our relationship and he has said to me that he feels stupid at times and he keeps getting shut down. I know he feels rejected.

This is the last thing I want the man I love to feel. It makes me feel so guilty and frustrated. I can't be the woman he married.

So I think to myself I'm only 39 years old am I just going to be like this forever. What

does it mean for my future and the future of my marriage? Is there no hope for me to get back the feelings I had before? Women like me who feel this way need a solution. We deserve to feel our sexual desire again.

Thank you.

DR. EGGERS: Thank you very much Victoria.

BEVERLY: Good afternoon. My name is Beverly. And Veritas arranged my travel here today. But I do have to tell you I would be here regardless; I'm quite passionate about the subject so I appreciate the opportunity that the FDA has given me to come here today and talk to you and tell you my story.

I'm hoping that hearing my personal story about how I've suffered with this medical condition will help you understand why women need help. I started out having this issue about four years ago. Initially I thought it was just going to be something that passed quickly.

It started because I had an allergic

reaction to a medication. Then my whole life changed. It basically turned upside down.

I saw over 30 doctors in a variety of specialties before I found treatment. I am about $35,000 into this issue at this point. I started with my personal gynecologist, moved on to my general practitioner, my concierge doctor, saw specialists at major teaching and research hospitals, sought out the help of top urogynecologists, endocrinologists and other specialties. I wasn't getting any help. But I wasn't going to stop.

I endured pudendal nerve injections because they might work. I was given anti-depressants which ironically make it even more impossible for you to orgasm. Anybody who didn't know that? Muscle relaxers, pain killers, I've a drawer full. Then I had life threatening things like face swelling, rapid heartbeat, major weight loss. No one could find the root of my problem. But I kept getting prescriptions for things that didn't help.

In case you are unfamiliar with the condition I'll share some of the things that I experienced as symptoms. They include, not limited to, but pain, depression, inability to maintain relationships, loss of interest, loss of ability to get aroused, low self-confidence, inability to achieve orgasm, inability to maintain relationships with your friends, your family. It really impacts your self esteem and you have to be an advocate for yourself because there is really no help out there.

I run a small business. I'm an entrepreneur. I have to get up every day and go out and interact with people at high levels in the community. I almost lost the ability to do that.

I adopted a daughter from Russia when she was nine years old. When this hit she was about 15 years old and needed me most. I lost at least three years with her. And I'll never regain that time.

I think the thing that makes me most angry and most disappointed is that if I went to

my doctor and I was a man and I said these things they would be able to write me a prescription within a couple of minutes for a drug that is insurance covered and FDA approved. I don't know how all their drugs got through approval but I'd like to know who is behind that.

I probably spent 50 hours in manual pelvic floor physical therapy thinking that might be the problem. And yes that is just as personal and intrusive as it sounds.

Fortunately for me I didn't believe all those other doctors and I didn't take all of those other drugs for any period of time particularly when they had life affecting threatening side affects like face swelling.

I found Dr. Goldstein and I received some treatment from him. He had the answers, he did different blood panels. He did some other testing. I even talked to a sex therapist in his practice who confirmed this was not in my head but a physiological issue and medical condition.

Prior to the onset of this I had a very

robust and fulfilling sex life.

Now that I'm being treated I don't have issues with arousal, interest, or orgasm. All of those things are possible. I have a great and supportive significant other. Unfortunately I lost a major relationship to this issue. And I never want to go back there.

The topic is never far from my mind. I'll never forget how it impacts my life. And I know it could come back at any time.

My significant other is very aware of how my symptoms wax and wane. He knows when my treatment is due. It is very evidence in how I initiate or how interested I am or how aroused I get. I can tell you for sure there is a direct correlation.

Recently I appealed to my insurance company who declined to pay for any of my treatments. We went to full third party medical appeal. Unfortunately they determined it was not medically necessary and told me that no future appeal will be possible. The biggest thing that

scares me is someday I might not be able to afford the treatments I get. And if I were a man every treatment I've gotten would be covered.

In closing I would just like to express that I was passionate about this and honestly quite angry about it as I started to prepare to come here to tell my story. After I was briefed by Sara from the FDA about my participation I honestly was dismayed and it became fairly profound. She was delightful to speak with when she told me about what to expect here today. Unfortunately when she told me not to set my expectations to high as nothing was likely to happen quickly you can understand that I was very surprised and more than disappointed.

I feel strongly that we need this to happen quickly. We need approval. We need doctors to get educated. We need people to understand this is a severe medical condition. And we need women to stop suffering in silence.

I know none of you want your mothers or sisters or daughters to go through this. It is an

unmet medical need. And no amount of talk therapy is going to fix it. We can't get better from a physiological need by talking about it. I would just be delighted if we had the same choices as men.

Thank you for the opportunity to tell my story.

DR. EGGERS: Thank you, Beverly.

And then Carol. Beverly if you could shut off your microphone.

CAROL: Good afternoon. I welcome the opportunity to participate in this meeting and tell my story. By sharing this experience I hope that it will assist and support women who are currently sexually dysfunctional as well as those who will experience it in the future.

I devoted a significant amount of time and energy on my quest for an answer, a solution, a treatment. I consulted numerous physicians and specialists and experimented with various pills, injections and topical medications.

My symptoms waxed and waned based on the

type of medication, its delivery system, dosage and the period of time I was on it. I experienced brief honeymoon periods when I was sexually functioning 75 to 80 percent. However, once the affect of the drug began to wear off I was back to where I started.

In my case there was an active interplay between my physical symptoms and the psychological aspects of my condition. For clarity sake I would like to discuss these separately.

A first and most frustrating symptom was the loss of my skin sensitivity. The skin numbness felt like my entire body was encased in a rubber glove sealing off all physical sensation. Another analogy would be having my body injected with a physical numbing agent like Lidocaine or Novocain. The second and related symptom was that I could not have an orgasm. I could not become lubricated, aroused or sexually excited even after sexual stimulation. No matter how intensely I tried I attempted to talk myself into climaxing, I never succeeded. I never succeeded and had no

history with this type of condition and never experienced sexual dissatisfaction in the past. I became so frustrated that any attempt to have sexual intercourse would end up in me crying.

The onset of both of these symptoms began when I was in my early 50s. It was a very gradual process over a period of months and became progressively more pronounced. It began with small subtle physical changes. The ability to be stimulated by being touched slowly disappeared. Sexual arousal and response time kept taking longer and longer until it became nonexistent.

I had difficulty coping with my new reality. Come to terms with the discrepancy between who I was and who I became. I felt sexually unattractive, inadequate, dysfunctional, isolated and asexual. My primary concern was that I would never be able to experience sexual pleasure again.

After several years, a significant amount of determination, patience, trial and error, and the support of an excellent physician

and the correct dosage of medication my condition finally stabilized. I'm able to climax, however, my skin sensitivity has never been completely restored.

Part of getting older is learning to accept the things you cannot change, the courage to change the things you can and the wisdom to know the difference.

Thank you.

DR. EGGERS: Thank you very much Carol.

And finally we have Karen.

KAREN: In 1971 at the age of 23 I had to make a careful decision about the type of birth control I would use after the birth of my first and only child. My mother-in-law had had a stroke at age 45 and was paralyzed for the rest of her life. She was in the first wave to use the then revolutionary birth control pill of the 1960s. My doctor recommended the brand new Dalkon shield IUD which was being marketed as the Cadillac of contraception. The advertising brochure I received boasted that it was 100 percent safe with

no general effects on the body.

12 years later at the age of 35 my reproductive sexual live and sexual life were forever altered when I had to have a total hysterectomy including the removal of my ovaries. During my recovery I learned that the Dalkon shield caused the cumulative damage from the pelvic inflammatory disease that went undiagnosed and untreated for 12 years.

The Dalkon shield debacle went down into history for being the most egregious breach of medical misconduct. The doctor inventor made a number of ethical lapses in the reporting of his research results. Tens of thousands of women suffered a wide range of pelvic damages.

I was please when I came through the building today to see a display case out front with former defective products and for all you to see the Dalkon Shield IUD, it's out there. At the time the FDA did not approve devices and it was precisely because of this case that the FDA began to approve devices as well as drugs.

My hysterectomy left me traumatized in shock, psychically devastated by the loss of my fertility and my precious highly erotic relationship with my husband. My bodily and psychic symptoms were severe for many years. I had a total loss of sexual desire and arousal. Orgasm was out of the question.

As I now know the loss of the sexual pelvic organs has a profound effect on sexual function. In the 1980s, however, doctors were still claiming that the only loss from a hysterectomy would be the ability to get pregnant.

My eventual recovery included retooling my career as a teacher to become a sexuality educator. I hope to educate other women about the sanctity of their sexual organs and how they could make more informed decisions than I did as a young woman.

Over time I was able to regenerate my sexual interest and capacity although I never fully recovered. At best I have been able over time to have what I call a feeble orgasm. I

incorporated what I had learned about positive sexuality and sensuality techniques to enhance my sexual experiences. However, there has always been an ebb and flow.

Life stressors presented challenges to my capacities. For me the loss of a good job, the illnesses and deaths of my parents, et cetera added to that ebb and flow in my sex life. Those stresses and the PTSD of the hysterectomy make my symptoms sometimes better and sometimes worse. At present I am dealing with the death of my dear husband. This loss has cause another major stressor to my sexuality a natural consequence of losing the love of my life.

The challenge of aging also presents an additional issue to my sexual functioning at this time. At the ripe old age of 67 I turned to my sexuality profession and became the cofounder of what is now the Sexuality and Aging Consortium.

Here is a warning, the boomers are coming.

[Laughter.]

Literally and figuratively and they, we, will demand sexual access in those long term care facilities that we may enter in a few years. Our society and health care community at large are ill equipped to deal with this phenomenon. So much ignorance pervades our stereotypes of old age.

For my part I accept the reality of my age and past challenges. I do not hold an unrealistic expectation associated with the cultural pressures to be forever young, beautiful and sexy. I, and many other women, young or old are not ever going to achieve the mind blowing nirvana of orgasmic ecstasy that saturates our popular culture. I am confident that one day I will return to a satisfying form of sexual expression whether it be self-love, wink wink, and/or partnered coupling. I don't think of myself as a cougar. I am more of a kitten. You won't hear me roar but if you listen carefully you might hear me purr.

Thank you.

DR. EGGERS: Thank you very much Karen.

I would like to extend a round of applause to all of the women up here.

[Applause.]

We know this is very personal to talk about and we very much appreciate that.

Unless my colleagues have any clarifying questions for any of the panelists, I'm going to grab a microphone and make my way to the front.

DR. KWEDER: Sara I do have a question.

DR. EGGERS: Yes, go ahead.

DR. KWEDER: Two of the panelists I think it was -- let's see it was Beverly and Carol both said they are currently being treated. I thought that is what you said. And so if you could say what the treatment is, if it is medication or some other form of therapy that would be helpful.

BEVERLY: Sure I am happy to share that. I am currently being treated with implanted testosterone pellets.

CAROL: I'm also taking testosterone but I am using a localized gel every day.

DR. EGGERS: And we will be addressing those products a little bit more in Topic 2.

Any other -- Marcea, please?

MS. WHITTAKER: Yes. I have a question for Beverly. Thank you again for your story. You mentioned that your partner knows when you need treatment. Can you expound on that a little bit?

BEVERLY: Certainly. I am more than happy to expound on it. The issue with arousal and interest is really what is at question here. And we have a very robust sexual life. But when I'm not interested or I'm not initiating or I'm not interested in his advances it becomes very clear that the pellet that is inserted in me is wearing off. Because we don't have any other stressors in our relationship, there are no issues in our life. And so the only thing that really comes into play is that treatment needs to happen again.

DR. EGGERS: Okay. So I'm going to start off by asking for a show of hands how many of you heard your own experiences reflected in at

least one of the panel member's comments today so far?

Great. Thank you.

Anyone who said my experience is nothing like what any of the women are talking about up here?

Okay.

At the end if we haven't addressed your different situations we'll come back to you. But I think that is reassuring that the range of experiences, we did hear a range of experiences presented this afternoon and we are now going to build upon that in a little bit.

We do have a polling question. Before we get to that I want to ask a few questions on terminology. And I'm -- many of you said that you experienced both in one of the first polling questions that you had, both difficulties with interest and difficulties with arousal. And if someone would like to share what's the difference between those two, how do you conceptualize those differently? If you are interested in sharing

just raise your hand and we'll come to you with the microphone; if you could just state your name; and if you have any of those disclosures to make.

MS. GOLDSTEIN: Hi, I'm Sue Goldstein. I paid for my own travel and what else am I suppose to disclose?

DR. EGGERS: If you are affiliated with any organizations that have an interest.

MS. GOLDSTEIN: Okay. I am here as a patient. But I'm also here as a sexuality educator and author and I've interviewed a lot of patients. I'm a clinical researcher so I have talked to a lot of patients and I'm also on the Board of the International Society for the Study of Women's Sexual Health.

I think as a patient differentiating between desire and arousal if you are interested in having sex or if you are receptive to your partner approaching you that is desire. When you are getting wet, when you are getting tingly, when you are having those bodily changes in bed or as you are approaching the bed I think that -- it is

the wetness that is the arousal. So while you have the interest and your body may be starting to get turned on, that is desire. But once you start getting your body actually changing, it is the getting wet, it is the -- maybe it is your nipples getting erect, your clitoris getting engorged, enlarged. Those bodily changes are the arousal. So I think that one of the biggest problems is you may not have an arousal issue but if you have no desire your body isn't going to be aroused until perhaps your partner starts stimulating you and then you have bodily arousal and then maybe you may have more interest. But the arousal can't just occur standing there looking at your hot husband or maybe you don't have a hot husband. I am married 40 years and I still think my husband is hot. But they are two separate things. But there is -- certainly there is an interplay but that doesn't mean that they are the same thing.

MS. EGGERS: We will be exploring that I think throughout our conversation.

How many of you did that -- did Sue's

comment resonate with that is how you conceptualize it as well?

Okay.

Any completely different conceptualizations?

Do you want to -- right here.

LEONORE: I think that it is enormously diverse. I don't think that you know all the words sounded good but I think if we sat down had a more personal conversation differences would emerge.

DR. EGGERS: And I think we should take this point to heart for all of the -- what was your name?

LEONORE: Leonore. We should take Leonore's point to heart for all of our discussion about just how variable and personal these will be to everyone.

So a show of hands if you could, there were a couple of panelists or maybe all of you who indicated that you used to have one kind of normal regarding your sexual experiences and now you face

a distinctly different normal, your experiences have changed. How many of you and if you feel comfortable raising your hand experienced that same thing where you had a one type of sexual experience and normal about that and now it is completely different.

Okay.

Are there any show of hands where this has been your normal for as long as you can remember that for your sort of adult life you've always been living with this normal?

Okay.

So most of you this has sort of had an onset; but we do have a couple of you who have been dealing with this most of your lives. That is helpful to set the context.

I'd like to go to a polling question now. And these are just again to start a discussion.

We'd like to know for those of you who experience absence or reduced sexual interest which of the following affects do you consider to

have the most significant impact on your daily life. And you can choose two. It is just a discussion starter including other if there is something other. So a) no or reduced interest in sexual activity, b) no or reduced sexual or erotic thought or fantasies, c) no or reduced initiation of sexual activity, d) not being responsive to my partner's attempt to initiate sexual activity. Or again other. Pick two that are the most important to you.

And on the Web we encourage you to answer the same question.

Okay. Well you've made my job difficult. We are going to be exploring a lot of these issues. So about equal numbers of a), c), and d) with less for erotic or sexual thoughts or fantasies.

So let's explore a few of these in a little bit more detail. And I'm going to start with the response to you partners initiation which is d) here. Any of you, you didn't just have to pick the polling choice for this. Any of you can

please comment on this. Are your sexual activities, this is maybe an easy question. Are your sexual activities typically initiated by you, your partner or both? You? Your partner? Both? Okay.

So it appears that the role of your partner's initiation is very important to your sexual experience.

How do you conceptualize when we talked about responsiveness to that initiation? When you saw this question what were you -- what was going through your minds when you said about being responsive? What happens? Can anyone describe anything that happens to you physically or mentally when your partner is initiating?

MS. PRICE: I'm Carla Price. The biggest thing that I feel is anxiety because I know that I'm not going to be able to respond back. So I just tense up, I'm anxious. And like one of the speakers said I definitely try to avoid it at all costs. So I'll stay up late. I get up early. Avoid any alone time. And my children are

married and out of the house so I don't have a lot of stresses other than this and it really shows.

DR. EGGERS: Thank you Carla.

Would anyone else like to comment? We had one over here. Anyone else? There in the back.

UNIDENTIFIED PERSON: I'll say hey, let me just finish doing the dishes or close my computer and make some space for this.

DR. EGGERS: And what is going through your head, if I can ask?

UNIDENTIFIED PERSON: Well, it hadn't occurred to me but it occurs to him so okay I'm open for that.

DR. EGGERS: Okay. Would anyone else like to share any kind of physical or mental responses? Yes, Beverly?

BEVERLY: It is interesting because what goes through my head is am I going to be able to orgasm during this and is that going to impact how he feels about our relationship because honestly that is a huge part of men's self worth if they

can get you there. And I've seen the wheels almost come off my relationship a number of times when that piece is lacking. So if I know my treatment is wearing off I tend to avoid sex because I know that that is going to create an issue.

DR. EGGERS: Thank you.

Let's talk about your own initiation. If it happens that you initiate sex, does your experience differ at those times than if your partner has initiated sexual experience physically, mentally or emotionally? Is it a different experience? Is it the same experience? Show of hands. Is it the same experience?

Okay. Go ahead.

BEVERLY: I would say it is a vastly different experience. If you are feeling aroused and you are feeling interested and you want to initiate sex the likelihood that you are going to have a successful exchange in bed or wherever you decide to have sex is much higher at least in my world. If I'm thinking about sex, if I'm

interested, if I'm aroused it is going to be a much more fulfilling experience that if I'm going along because I was doing the dishes and I can figure out how to make time for it.

DR. EGGERS: Okay.

BEVERLY: And so that just depends on how you are being impacted by the arousal issue and interest issue.

DR. EGGERS: Okay. Does anyone -- does Beverly's point resonate with you?

Okay.

Any final -- anyone want to build upon that?

Go ahead, yes.

LEONORE: I think that Beverly's experience is idiosyncratic to her, not unique, but I think other people expect that when they respond but don't initiate that there will be longer foreplay and that if that has been communicated with their partner the foreplay will be choreographed to fit the situation.

DR. EGGERS: Thank you. I think there

were a couple of hands over here.

KATHERINE: Hi, I'm Katherine. I don't want to say this really because my husband is sitting right next to me but I can tell you that when he does initiate my response is kind of sigh] and that is both mentally and physically. My body really doesn't do anything and nothing happens to me mentally or emotionally either. And I actually don't ever initiate sexual activity since this happened so it is kind of hard for me to answer your follow-up question to that.

DR. EGGERS: Is it hard for others to answer the follow up question, like Katherine said?

Go ahead Victoria.

VICTORIA: I have to say I 100 percent relate to what she just said and I felt the same way. When you asked that question I was king of going I never initiate so I don't even know anymore.

DR. EGGERS: This -- what makes the questions that we are asking difficult for you is

as much as we want to know what the answer to the question is. So please feel free if we are asking the questions in the wrong way you can alter them to fit your experience, so feel free.

We have a hand right here.

CARMON: Hi, my name is Carmon and my trip was funded by Veritas but like Beverly I would have flown here without that. I am really excited that you are doing this.

My husband and I have suffered for over 30 years with my low libido and I did get treatment which has helped me tremendously. And for the first time in a long, long time I do initiate sex sometimes. And for my husband that is a wonderful blessing because he knows that it is not duty sex but that I actually want him. And he wants me to want him. And I think that most partners feel that way about their sexual relationships. So it does make a big difference that I'm able to do that now.

DR. EGGERS: Thank you.

Who else? Here.

SUE: It is Sue again. I think one of the problems that I know occurs for me is that even if I'm willing when my husband initiates to have sex I can't stay in the moment necessarily and then your body stops responding. And even going into the bedroom is like am I going to stay focused today, am I going to have an orgasm today. It is like you feel sometimes like why waste your time having sex if nothing is going to happen but say okay I'm willing to try again, I love my husband. Essentially it starts out being duty sex and if you are lucky it turns into great sex. I'm in my 60s and sometimes sex is the best it has ever been in my life because like some of these other women my children are grown so I don't have those kinds of stressors. But sometimes my body just betrays me and it doesn't respond or it responds but then if I can't stay in the moment and I've taught myself to refocus back, sort of my own version of mindfulness. But it doesn't always work. And that is a really hard issue to deal with. And there are times that like Beverly when

my -- I have a testosterone pellet and when it is fresher and newer my body -- I am more interested and when it is getting later my husband can also tell. He goes, go get your blood test; it is probably time for a new pellet. And we never know when we can count on our minds and our bodies.

DR. EGGERS: Thank you Sue.

One more right here and then -- oh, we will do two more. One more right here and then one more in the back.

AMANDA: Hi, I'm Amanda and likewise I signed up to be part of this discussion before I found out that my travel could be funded by Veritas. But in response to the question I agree with what everybody said. Obligatory sex is a far cry from initiating and I think for years the burden of a healthy or a regular sexual relationship has fallen on the men particularly my husband. And I think that they've sort of got the bum rap and women have too. But unfortunately in the lack of desire that is what it falls down to. So in the short amount of time that I was treated

it made a dramatic difference for us as far as my initiating and I can tell that it definitely elevated our whole level of intimacy and the way we related to each other. Once I stopped it returned to normal and unfortunately the burden falls in his shoes. But I think it would be interesting one day if you guys could pull some men and get their thoughts on the process.

DR. EGGERS: All right. Thank you.

Okay. One more back there?

THEA: Hi, my name is Thea. I have no funding to be here. I know for myself and many of my friends growing up we sort of learned not to initiate sex because some of our boyfriends made fun of us or I know there is a stereotype that men are always wanting sex but that wasn't always my experience. And also it took us longer to orgasm and we found that embarrassing and wondered if we were normal because in porn, in culture, in Hollywood movies it seemed very easy for women. So there was a lot of shame around that.

DR. EGGERS: Thank you very much. Leah,

right? Thank you

Let's move on to the next question that focuses on arousal. For those of you who experience absent or reduced sexual arousal which of the following affects do you consider to have the most significant impact on your daily life? And here again you can choose up to two. No or reduced sexual excitement pleasure during sexual activity? No or reduced sexual arousal in response to written, verbal or visual cues? No or reduced genital or non genital sensation during sexual activity? Or other?

Okay. So the top two in terms of frequency here no or reduced sexual excitement or pleasure or no or reduced genital or non genital sensation during sexual activity.

On the Web can we get a sense of what the responses were?

MS. GIAMBONE: Sure. 50 percent of the people on the Web said no or reduced sexual excitement or pleasure during sexual activity. 40 percent said no or reduced sexual arousal in

response to written, verbal, or visual cues. Followed by 30 percent with or reduced genital or non genital sensation. And then ten percent said other.

DR. EGGERS: Okay. If you are on the Web it sounds like a few more of you talked about arousal in response to written, verbal or visual cues. Send in - - type in a comment to that.

On the Web did I ask about what the responses -- did they look similar to that first question I asked?

MS. GIAMGONE: Yes, very much so.

DR. EGGERS: Very similar. Okay. So let's go into a little bit of these issues in a little bit more depth. How do you differentiate between the terms excitement, pleasure, sensation, arousal? Do you tend to use -- do they mean very similar things for you? Do you prefer one term? Does one term arousal or excitement or a different term resonate for you?

We will go with Karen first.

KAREN: I forgot to disclose that I have

not received any remuneration of any type to be here.

I think in my opinion that question is incredibly varied and everyone is going to be using a different word to describe what is either psychological or physical. Excitement, arousal I mean pick a, b, c or d.

DR. EGGERS: Then can I follow up. Does it make it difficult to answer these questions and identify which one of these would be most important to you given that they all use different terms?

Following up on what Karen said. I see some head nodding.

So if I ask about the sexual excitement and pleasure during sexual activity would someone be brave enough to explain what are you conceptualizing when you did respond to that one? Is it the sensations? Does it include orgasm? You know this is a very tough subject to address and so we do appreciate all of your thoughts and experiences.

Well if you do want to comment on that and work it in somehow, feel free because we do know it is difficult as Karen was saying.

Sure go ahead.

LOUANNE: I'm Louanne and I am a patient and I am also a therapist. And my travel was paid for by Veritas.

The way I look at it from the therapist mindset sexual excitement is what you make out of what your body is feeling. But sensation is what you actually believe you are feeling and it is the transmission of the nervous impulses that you go, oh, I feel that, it is muted; it's less than I felt before but I feel that. And then I think a) is what you make of what you are feeling and how pleasurable you categorize it for yourself.

DR. EGGERS: Okay. Thank you. Anyone else want to comment?

Yeah, right here.

DR. PARISH: So my name is Dr. Sharon Parish. I'm President of the International Society for the Study of Women's Sexual Health and

my travel was supported by SPROUT.

I think looking at the distribution of responses here. I think it is very important to understand the age range of the women both in the teleconference and also in the room. And c) is going to be very different in a younger versus an older woman. And I think this differentiation in understanding these responses is very critical to understanding this diagnosis in patients here and in our offices.

DR. EGGERS: Do the FDA colleagues want to follow up on any aspects of what we've been talking about interest or arousal?

Yes, Christy.

DR. CHANG: I have a question on response b) actually. So even though it didn't get as many votes as either a) or c) I'm just wondering if any of the ladies could clarify for us what kind of written cues, verbal cues, visual cues or even tactile cues may help in helping to reduce the difficulty with arousal?

DR. EGGERS: Okay. We'll go with Karen.

KAREN: Well as a sexuality educator I am very interested in finding ways to become the best lover you can become. And for some people that is looking at erotica. For some people in response to your question that is using sex toys of all kinds, either alone or with your partner. It is so again varied in the ways that you can besides just being anxious about it that you can learn to be a good lover and to accept the limits of what you are able to achieve or accomplish without feeling like a failure.

DR. EGGERS: Does anyone else have another follow up. We have one here.

NATALIE: Hi, my name is Natalie. I received a travel stipend to be here today as well from Veritas --

DR. EGGERS: Can you talk a little closer to the mic. Thank you.

NATALIE: I have a thought about arousal and desire that occurs to me. I used to have a normal sex life my whole life and then this happened. It was a year of going through hell but

I am now being successfully treated. And so the question about desire is basically before -- it is not a matter of how much foreplay we do or not. I'll be approached and we can spend forever trying to make something happen. And the difference is the desire within me. It is very obvious for men when it is working and not because they are able to have sex. I am able to grit trough it which I often do in terms of like I do it for him but not for me. So the loss of the desire is what I think it is important to make that distinction. It used to be there. It is not anymore unless I keep getting treated every four to six months.

DR. EGGERS: Thank you very much.

Yes. Sandy.

DR. KWEDER: If it is okay can I probe one of the responses.

DR. EGGERS: Oh, of course.

DR. KWEDER: I can't see the woman who is the head of the society, there you are. Can you say a little bit -- can you expand a little bit on the comment that you made about some of the

differences you might expect or expectations for some of these responses based on age range. Can you comment on that a little bit?

DR. PARISH: Sure. Absolutely. So I was referring to item c) no or reduced genital or non genital sensation during sexual activity. You know both organic diseases that are sometimes co morbid with older women such as diabetes, hypertension and other neurologic conditions or genital symptoms of menopause related to vulvar and vestibular changes may result in changes in genital and non genital sensation during sexual activity. So I think looking at the spectrum of responses has to be in the context of understanding we have a distribution of ages of women in the room and it might be useful to separate that out.

DR. EGGERS: Yes, Marcea?

MS. WHITTAKER: I have a question and Sara actually asked it and I think it is important as we move forward. The question was when we think about excitement and pleasure and arousal

does that include orgasm. And so we can maybe just do a show or hands.

DR. EGGERS: Sure. So if in those set of terms you would include orgasm could you please raise your hand if you feel comfortable.

Okay.

If that term doesn't need to be there, is not included in that, I'll assume the rest of you? Raise your hand.

It does not need to be; is not a part of that? It can be but doesn't have to be; raise your hand please.

Okay. Seems like a majority. Thanks for clarifying.

I wonder if we can go back to this question here about the age range. Can I ask how many people who indicated c) about the sensation -- - I have to do some math here -- how many of you are 40 and less? Let's take 51 and older? How many of you answered c)?

Okay. And younger than 51?

Okay. So we obviously don't have

exactly the spread but it does say that there is a difference. At the break we'll try to see what the clicker responses were and go back. We might mess up some technology here. We are kind of one direction.

DR. MODJOROS: Hello, my name is Melanie Modjoros. I'm a physician and a sex therapist in northern Virginia. I have no financial interest to disclose.

And I think this is a very interesting question. Every woman conceptualizes it a little bit differently. From my patients sexual excitement is often akin to the building of an orgasm but not necessarily the actual orgasm. Sexual pleasure is usually included in that building but, of course, the pinnacle is the orgasm and the climax that most men and women are looking for.

The sexual arousal in response to written, verbal, and visual cues can be in a solo setting or in a couple setting. And that is different because if a woman hears and I've heard

this from my patients, if a woman hears her husband say something sexy or naughty in her ear that may turn her on. That may result in arousal instantly or not instantly and that may change and that may cause distress.

So these answers are very heavy. They are very dense. And teasing it out even more I think would be helpful because every woman experiences it a little bit differently and every woman and couple conceptualizes it differently.

DR. EGGERS: Okay. We can take a couple more and then we will move on. But while we are getting the mics over there I'll encourage everyone, I think my colleagues would agree to write about this in the Docket. Write about how you make those distinctions and you can really expand upon it there. That would be very helpful.

We will take one more and then we will move on to other symptoms.

UNIDENTIFIED PERSON: When you asked the question about do we include orgasm in the concept of sexual pleasure, I think you got few answers

because we were confused by the question a little bit.

DR. EGGERS: Okay.

UNIDENTIFIED PERSON: And then someone added in well it doesn't have to always happen, it can be included and I think that is a very dense question that needs to be teased out to because it winds up that if a woman has never had an orgasm it is a bit like going to a movie and always leaving ten minutes before the movie ends. And after a while you stop wanting to go to the movies. And so for some people who know that orgasm is an option and it is an option that they can have relatively easily then it is not as crucial of a factor. But when it is never a factor then it is a very crucial one. So I think we kind of blended all of that together when we were raising our hands about that.

DR. EGGERS: Okay. Thank you. Thank you for the clarification.

Let's move on to other symptoms that are beyond arousal and interest. And then we are

going to be following up on sort of the sexual event. So we are going to be coming back to that.

There were some others in both of these categories. Actually let me -- I'm going to give a shout out to the folks on the Web. Before we get into other symptoms is there a brief summary we can have of comments on interest our arousal from the Web?

MS. GIAMBONE: We haven't heard too much on the symptoms. We've heard more impacts coming through.

DR. EGGERS: Okay. We'll wait for impacts at the end.

MS. GIAMBONE: Sure.

DR. EGGERS: Now let's talk about other symptoms. What was included in your other? Anyone willing to share that?

Okay. Just so we can tease out some of the other aspects of FSD that you might have, can I have a show of hands again for how many experience something other than -- you have interest and arousal challenges but you also have

one of the other aspects of FSD, pain or orgasm or headaches or something else?

Would you like to expand upon yours a little bit Carla?

MS. PRICE: I'm Carla Price and I failed to mention that I am funded through Veritas but I would have come otherwise.

My problem is coital headaches, so as my arousal builds often times I experience just an unbelievable migraine that is worse than any migraine I've ever experienced. So it doesn't happen all the time but more often than not, so some of my low libido might just be the fact that there is pain waiting at the end. So it is painful pleasure I guess you might say. So it's not real fun.

DR. EGGERS: And Carla if I might follow up a little bit then. If your headaches did not -- if there is ever a time when your headaches do not accompany your sexual experience, is your interest and arousal still affected? Does it return?

MS. PRICE: No. I actually have to say that I still have a decrease in arousal. The one thing that -- I have been treated a little bit and it has helped about 50 percent but again the arousal -- the desire seems to be an issue. Which I do want to add I like the comment I would love to look at the husbands and partners views. It has come to the point where my husband doesn't even want to initiate sex because he is afraid that he will hurt me because of my headaches. So he said what fun is it for me to cause you such pain. And so our marriage and relationship has been really rocky. And it is -- I mean it has affected his self-esteem and his manhood. So it is definitely a domino effect.

DR. EGGERS: Thank you, Carla.

So I think we have another opportunity for the Docket comments which is to ask your husbands to submit -- your partners to submit a comment, invite them to. We would like to hear from men as well on their perspectives on this.

Would anyone else like to talk about any

other symptoms particularly as they relate to or how they affect interest and arousal?

We have Beverly and then we'll go back there.

BEVERLY: I just want to say that I don't know if these are all physical things and so if I'm reading the question most significant impact on your daily life and I covered that a little bit when I was speaking because I think there is a whole myriad of other things that it affects. Most often it affects things like my self confidence and how I approach the world and how I feel about myself and what I project to other people. So I don't know if anybody is thinking about that because the multiple choice answers that you offered were really so specific to being aroused or to being interested or actual intercourse.

And I think that other category can take into account a whole lot of other things that I'm sure a lot of women in this room experience. But we are so focused on how it actually works with

actual sex act that it is not -- they are not bringing in this whole other area.

DR. EGGERS: Okay. So maybe I'll go a little bit astray on this and say if you knew that anxiety could have been one of your choices, how many of you would have put anxiety as it was described. Someone described anxiety here. How many of you would have put that in your top two?

Okay. Several. And we had -- we did hear about it earlier is your experience the same as what we heard about which is a physical anxiety that happens when you think about desire or when you think about arousal or when initiation happens?

BEVERLY: The problem with that too is when you take that to any physician and you tell them you have anxiety or you are depressed about it, they give you an anti-depressant which then inhibits your desire and inhibits your ability to orgasm. And so it ends up becoming a circle.

DR. EGGERS: Okay. Great.

I do want to go back there; there was a

comment back there.

JUDY: Hi. My name is Judy. And the Social Sciences and Humanities Research Council of Canada paid for my trip. I'm here as a researcher.

But my research is on language in particular, and in particular language relating to health, medical conditions and this one in particular which I've studied for a while. I find it interesting how central the language of symptoms is. And it is a word that you keep using. And I think that the idea that these are symptoms suggests that there is an underlying disease and that that is kind of the position that we are starting from even though we are talking about variety and experience and the DSM criteria are kind of more open than that in fact. And so I wonder what would happen if we stop using the language of symptoms to talk about everything we're experiencing.

DR. EGGERS: Would it be better for the purpose of discussion if we used the term aspects,

that should cover everything, so I'll try to use that term moving forward; can't promise it. But I'll if I think of it I'll try to use that term. It sounds like that is a more appropriate term.

Are there any other aspects of interest and arousal that FDA wants to follow up on?

MR. JOFFE: I had one question. I think it has come from a few people that treatment can kind of make some of the arousal and desire wax and wane. But I was wondering for those of you who maybe aren't on treatment or even those on treatment could separate it, trying to get a sense of what arousal and desire is doing in general. Is there a waxing and waning over time or do you feel it is kind of a steady state of where you are all the time with this condition?

DR. EGGERS: We will go with Vicki first.

VICTORIA: I had treatment when I first went to see Dr. Goldstein he did -- I got the testosterone pellet and it did work like some of these women are saying for a short period of time.

But it wasn't in my budget to keep going back and flying back to see him and it wasn't offered where I live. So I am currently not on any treatment. And I -- when I was on the treatment it helped a little bit. And now I am just back where I started and my symptoms are pretty constant and they don't wax and wane. It is the same every day.

DR. EGGERS: Can I get a show of hands for how many people share the same experience as Victoria?

Okay.

Karen did you want to follow up on that?

KAREN: Well I guess it is again and my role as a sexuality educator that the way that can be dealt with these things is to enlarge your perspective beyond the -- as I call it in my classes, the stairway to heaven -- [Laughter]

KAREN: -- which is a lockstep way of going and getting to the ultimate orgasm. And there are from personal experience a lot of outer course sensuality based communications and

experiences with your partner that can reduce the anxiety and the pressure of having to go all the way to the top.

DR. EGGERS: Okay. Thank you.

We will be revisiting this in more depth in the next discussion about treatments in general.

I want to tee up the phone to see if there is anyone in particular on the phone who absent treatment you experience waxing and waning of symptoms; that would be useful to hear about.

Did anyone -- we asked about absence of treatment, no waxing and waning or a constant symptom, is there anyone who does experience a waxing and waning of -- sorry, aspects, of their condition over time. Okay. In the back there.

THEA: Sorry, I mean I think that it is fair to say that desire waxes and wanes as a normal state of human physiology and being. I'm also a sex researcher and that is what all of the evidence points to.

DR. EGGERS: Does anyone have an

experience they can use to illustrate that?

SUE: I think one of the confounding facts of that question is a lot of us are on therapies that are not constant. If you are taking a daily testosterone gel for instance it is relatively constant whereas if you are using a pellet it forces the waxing and waning. But I think in addition that for some of us who are older things change as well. I know I interviewed a lot of women for a book I wrote and one of the women said it was like a light switch turned off. She just lost all interest, all desire; and it didn't change whereas for me it was something that happened slowly over time and then for me with time for treatment I was better and now as I am getting older I have been on treatment for 13 years, I was diagnosed 13 years ago and now I find that testosterone alone isn't enough. I have changed. But it is not a daily waxing and waning per se but it is a slow change so I think we really have two kinds of patients; those who just one day everything changed. I think Vicki said it

after her fourth child everything just totally changed whereas for some of us it is a slower progression.

DR. EGGERS: Thank you very much.

Go ahead, right there?

MS. KINGSBERG: Will all due respect to the normalcy of desire -- I'm Sheryl Kingsberg; I'm a psychologist and professor in reproductive biology at Case Western Reserve. I think the premise of this whole meeting is about an unmet medical need and that we've all agreed that this is a condition that we are working to find treatments for. So I think symptom is appropriate and I think it does a disservice to the women who have come all this way to talk about their condition and their symptoms to be respectful of that. That this is really very distressing.

DR. EGGERS: Right here. Yeah, if you could state your name and indicate -- there was a hand right here. And make your disclosure please.

BEN: Yes, thank you. My name is Ben and I'm here with my wife. Veritas did pay for our

travel. This is an issue that is very important to us. A couple of people have mentioned the impact on the man in the relationship and I can speak from personal experience. And it does have a huge impact when your lover, your soul mate is no longer interested in having sex with you. We've experienced the waxing and waning but it definitely affects the man. Again I know it is primarily about the woman but it affects the man, it certainly affects your ego, how you feel about yourself and it affects the broader relationship. So it has broader implication than just the man and the woman. It actually affects the relationship in the entire family.

DR. EGGERS: Thank you.

All right. I have a question about symptoms or aspects and their changing over time. We heard mention -- I can't remember -- I don't believe any of you mentioned this but in the comments that were sent to us a few people mentioned keeping a log and a diary, a daily diary every day. Does anyone keep a diary of their

condition?

Here, yes, can you explain what you put in your diary?

MS. REED-HOFF: Oh, I use a topical. I'm Judith Reed-Hoff (ph) and Veritas handled our travel arrangements, thank you very much.

I use a topical EstroGel and Testim and so then I record every day what the volume is that I administer to myself and then when it gets -- I feel out of whack then usually I know it is time to have my blood test done because Dr. Goldstein is very emphatic about following up anywhere. I started off at three to four weeks and now six to eight weeks.

DR. EGGERS: So if you were asked to think about tracking your symptoms over time; does anyone track those over time just as a natural thing that you do?

You track symptoms, too?

JUDITH: Yes, I do, I track symptoms because I think it is important that I know because sometime we think we are feeling okay but

if you write it down it makes a lot more sense and you can look back and say okay this was not a good day or a good evening and then I'm able to know what to do from then on.

DR. EGGERS: Was there -- yes, Carol?

CAROL: When I was being treated at the beginning of this experiment I kept a diary religiously and I did symptoms every day and the reason I did that was when I went to see my physician we would look for patterns that the symptoms are a lot of times related to the amount, the dosage of medication that you are on. And when you are not on enough you are going to become symptomatic. And when you increase it a little bit it resolves the problem until you get to the next hurdle. So it was very useful for both me and the doctor that treated me.

DR. EGGERS: Okay. So I think what we are hearing is that the tracking of symptoms over time is in large part due to finding the right treatment or dose for you. But I imagine the same sort of aspects apply to the question that I'm

going to ask so I am going to ask first I'm going to ask this question.

Knowing that you would want to track your symptoms as accurately as possible, how often do you think you would need to report in order to remember those symptoms accurately?

Okay. We have very clearly -- well, we've made it clear that this is dependent on if you are on a treatment. But I'm going to ask you to when you answer the question just say whether you are on a treatment or not and answer the question -- anyone to answer the question about what time period do you need. Do you need to record them daily, weekly, monthly, et cetera?

We have one hand here and then we will go on to others.

AMANDA: I am not currently on a treatment. And I myself at times did keep track of symptoms but what I found unfortunately was daily was not important because to me as time went on it was the broader picture and the longer range and it actually became more depressing and distressing

to think about on a daily basis. It sort of became the new norm which really was not acceptable. So my goal was the long term affect and how it was affecting me.

So conversely you have really good sexual experience when I was being treated you don't also need to record that because you don't forget that and especially as few and far between as those occurrences were that was more critical and more important that I track than a daily occurrence because to me it became the new norm.

DR. EGGERS: Okay. How many people does it resonate for what Amanda said?

Okay. Any different experiences? We have a hand here in the back.

LEONORE: You know it's -- we're talking about treatment and we've only been talking about certain kinds of medical treatments. So let me just say that non-medical interventions: psycho-therapeutic intervention, psycho-educational interventions. These also involve a certain amount of paying attention to what is going on in the

relationship and paying attention to what is going on in one's moods and in one's body. But it is done in a completely different way because attentional focus is really reframed in some sex therapy, sex therapy that I do as a problem so that you don't want to get obsessionally preoccupied with self monitoring. So I'm finding this conversation a little difficult. If we could talk specifically about medical interventions and how you deal with reduce arousal and paying attention and this and that but it is done quite differently with psycho- therapeutic interventions even though one could pay attention to symptoms or aspects. But one tries to get away from obsessional self focus as the magnifying problem rather than a useful intervention.

DR. EGGERS: Okay. I think there was another hand up and I'll turn and see if there are any follow up questions to that. Thank you very much.

KATHERINE: I actually had never even thought of the idea of keeping a diary or a log of

my symptoms because as someone mentioned on the other side of the room I was one of the people that had the switch flip in my head. And I had it one day and the next day I didn't.

And when I just realized my feelings were kind of always that way I felt no need to write it down because they are the same every single day. There is nothing dynamic. There is no waxing or waning with me. And I'm not on any treatment. So --

DR. EGGERS: Thank you very much Katherine.

Are there any follow up questions?

OPERATOR: We have one question from Maria.

DR. EGGERS: Okay. Let's go to the phone.

Yes, operator. Yes, Maria, hi.

MARIA: Hi. How are you?

DR. EGGERS: Very good, thanks.

MARIA: Good. I have a question in reference to the treatment from a physician

standpoint. [Garbled.]

DR. EGGERS: Maria. Can I interrupt you for a second? Can you hold the phone further away. Let's see if we fix the sound quality.

MARIA: Okay. One moment. Is that better?

DR. EGGERS: That is better, yes. If you could just briefly recap what you were saying?

MARIA: One moment. I will take it. Can you hear me?

DR. EGGERS: Yes.

OPERATOR: Much better.

MARIA: Okay. Great. I was saying that when I was treated, I recently had BioTE which are the pellets done. And I had to actually change physicians because my OB Gynecologist, the doctor I had been going to for the last 50 years did not agree with the actual treatment due to the information that had been submitted to them of the year in terms of the danger and why wouldn't -- and all of the information that comes across I think that our practitioners are well informed. I

gave my practitioner with information and I am just like looking over the Internet. How can I fix my problem? I am like when is in Vitro coming out? Why can't Flibanserin -- why can't those drugs be approved? What is the issue? I mean my depression --

DR. EGGERS: Hey, Maria, I am going to interrupt you at this point because we are going to be talking about those issues in our afternoon discussion. Did you have anything that you would like to contribute about the symptoms you feel particularly as they change over time?

MARIA: Yes.

DR. EGGERS: Okay. Thank you.

MARIA: My vaginal dryness is there. I didn't use to have that issue at all. In terms of anxiety building up with the thought of sex that has increased immensely which is a deterrent for me having sex and a deterrent for my husband fulfilling sex.

DR. EGGERS: Okay. Thank you very much.

MARIA: Okay.

DR. EGGERS: Do we have one more person on the phone? No. No we don't. Okay.

We have a few more minutes. And let's first see if there is any Web comments that have come in particularly on the ideas that we've been talking about changing or not changing over time.

MS. GIAMBONE: So we have heard a few symptoms mentioned; disinterest, repulsion, intense pain that has brought tears. And then in terms of changing over time one participant commented that for her the challenges were in the beginning of her sexual experience and then sometimes the challenge would be reaching an orgasm so that it varies throughout the experience. And then other factors, we heard a few factors on feeling guilty and feeling as though their partner felt as a failure that they couldn't please -- satisfy.

DR. EGGERS: Thank you.

I want to ask a few questions about engaging in sexual activity. We've talked about that some. But I have a few directed questions

about that.

So if you were asked to rate whether your last sexual event was satisfactory or not satisfactory what would go into this determination? I realize this is a very hard question so you can change the question if you need to. But what we want to know is what goes into a determination of whether a particular sexual event, however -- you've determined that you've had sex of some sort. How do you determine whether that is satisfactory or not to you? What factors into that?

Okay. Karen, please.

KAREN: Well it depends on what your expectations are for the outcome.

MS. EGGERS: So your expectations. Have you expectations -- show of hands if your expectations now on what you would consider a satisfactory sexual event has changed than when before this happened?

Show of hands? Okay. So within this new set of expectations is it easy to tell whether

a sexual event was satisfactory or not?

Katherine I don't want to pick on your but I see you might have something to say.

KATHERINE: It is a success if he is having a good time because it is out of obligation for me and I have no expectations. I might not even want to have sex but if he wants sex then and I give it to him then, yes, I was a good wife today.

DR. EGGERS: Does that resonate with others?

We have one comment here and then we will go to the back.

MS. MODJOROS: As a sex therapist I deal with the idea of satisfaction a lot and satisfactory sex. I would say that the majority of my patients that is not the goal. They are not looking for satisfactory sex. But if you ask them specifically what it is that they would find satisfactory sometimes you get incredibly sad answers. Like a woman who says she doesn't want to cry after sex. A man who says I just want to

feel desired. And so looking for satisfactory sexual experience I think it is not the goal of the average adult. And I don't know that it should necessarily be the goal that we are looking for either. Probably satisfying, not satisfactory but satisfying sex and good sex and where emotions are pleasant afterwards would be a better goal at least for the patients I see.

DR. EGGERS: As a follow up I'm going to ask a show of hands. To follow up on this a show of hands if achieving a satisfactory sexual event is a meaningful aspect of your overall condition?

Okay. So it looks like for several of you that is true.

There were a couple of hands raised over here.

MS. WATSON: I'm Lauri Watson and I'm a sex therapist. I paid for my own travel.

I think that when women tell me, I've treated at this point hundreds and probably thousands of women with low sexual desire, and when they talk about what is satisfying it isn't

just necessarily an orgasm, although I think that is hard to understand if the goal is orgasm for perhaps a male partner, they'll say yes, I got aroused, I reached an orgasm. But what is missing for them and I'd like to split apart again desire and arousal. What is missing is they didn't necessarily want it. They didn't desire it in the first place. And that is subjective sense of desire is often very missing and feels difficult for them.

Thank you.

DR. EGGERS: One more over there.

KELLY: My name is Kelly. And I paid for my own travel. I agree with the two ladies here. It is -- there is no wanting to have sex. There is no -- and it is very difficult when you do have it it is out of obligation whether you want to admit to it or not. And it is difficult that it is. And I would say something that would end up being pleasurable would be the fact that when it ends your husband doesn't automatically think it was out of obligation. And it is

difficult, as the gentleman said, it is difficult for everybody. It doesn't just affect the female. It affects the male and their mental state which affects your relationship which affects how you deal with your kids and it affects how you deal with everybody else and how you think of yourself. It is an encompassing thing and to have to try to write it down every day is discouraging and depressing. So I think -- I know that kind of answered a bunch of different questions.

DR. EGGER: Karen and then we will go to Amanda and then I have a follow -- I have one wrap up question.

KAREN: Are any of you aware of the faked orgasm?

[Laughter]

DR. EGGERS: That was a rhetorical question.

KAREN: Well the laughter in the room sort of indicates that it is a phenomenon for all women to want to please their partner or think that their partner wants them to have this

orgasmic nirvana kind of feeling. It makes me wonder how many partners have actually talked to each other either at the beginning of a relationship or during their relationship about what pleasure they would like to have and how they can give it to each other. And for some people outer- course is much more pleasurable than intercourse and the discussion here has been focusing on intercourse and orgasm.

DR. EGGERS: Thank you.

KAREN: But how do you know what really pleases your partner most. It may not be that cultural stereotype, again as I've been commenting on that orgasm is not the necessary goal for all people.

DR. EGGERS: I will just reiterate that the Docket is -- it would be a great place to -- we would like to hear across the spectrum about what your goals are in your sexuality, your sexual experience. So I'll encourage you to contribute a Docket comment and include that.

We'll go to Amanda and then I have one

question to wrap up.

AMANDA: I agree with what Karen was saying in that for me sex is not just about orgasm. I mean a successful or satisfying event for me is more about feeling connected to Ben and being close and feeling arousal. But it is also on the desire component of it is that I can have sex, it is not an issue being able to have sex because I can perform any time. The difference in desire is that comes from within and that makes me feel alive and like a woman and desirable and feminine and that is the aspect I think I bring to Ben when I'm feeling that which is not very often and so I think that is the difference between a satisfying sexual event that has desire accompanied with it because I feel like I am contributing.

DR. EGGERS: Great. And I see some head nodding.

We will go to the Web. Are there any final comments particularly ones that haven't touched upon something not addressed yet?

MS. GIAMBONE: We did hear a few participants comment on factors that they felt have led to their FSD including age, body image, boredom and then another participant commented on having more research on attitudes on sexual behavior specifically for residents in nursing or non nursing home settings. And finally we had one other comment on one participant commented that she has to pretend to enjoy it for her husband.

DR. EGGERS: Thank you.

It is very clear that coming up with questions to appropriately ask on such a challenging and personal and variable condition is difficult. So I am going to put a thing out for the Docket, too. If there -- if you are writing a Docket comment and you are like oh, I wish this questions would be asked or this is how you would have gotten really good thoughts about what is most significant to women's lives. Here is a question I'd ask. That would be very helpful. I think it would help FDA as we think about furthering moving forward and asking women

questions about this very personal tough subject.

So with that I'm going to say that we are finished with Topic 1 on the most significant symptoms. We are going to be into Topic 2.

Let's come back at 2:35. But before you -- can everyone in the audience give a round of applause to all of the women and men who shared their experiences.

[Applause.]

DR. EGGERS: Thank you so much. We'll be back at 2:35.

(WHEREUPON, a break was taken.)

DR. EGGERS: I am going to ask you to please make your way to your seats and the Topic 2 participants if you could please make your way to the panel table.

Okay. All right. This is your last call to make it to your seats, please. We do want to make sure we have a rich discussion two.

And again as we get ready for discussion two I am going to ask the discussion two panel members to come up.

Okay. Any of the other Panel 2 discussants? Okay. Thank you.

As we work our way in I'll just recap the bridge between Topic 1 and Topic 2. We had a very rich discussion on the complexity of FSD in the previous topic and my colleagues have given me the head nod that we are getting very useful information on that complexity and on what matters to you and what's most significant to you both in your sexual experiences and as we've heard through your comments regarding the distress that you feel with this.

So as we move into Topic 2 we're going to focus on current approaches to treating FSD. Again with a particular focus on interest and arousal. We have touched upon some treatment issues already. It is unavoidable to have touched up on that in Topic 1 because they are intertwined, very difficult to untangle. We hope to do that now. And as we go through our comments it is going to be important that we can talk about symptoms on treatment versus off treatment,

whatever that treatment is that you are going to be talking about.

So we are looking at what you are currently doing to treat your conditions or symptoms? How well those are addressing the most significant symptoms of your condition. How your treatment regimen has changed over time? I think we've gotten a sense of that. Any downsides? And really importantly we'll save quite a bit of time for this is what would you look for in an ideal treatment for your condition? What symptoms would you most like to target? And what would you consider to be a meaningful improvement in the symptom.

And with that thinking about this question number six I know that we all know that specific treatments will be mentioned in the course of this discussion and that is appropriate. We will do so. It is unavoidable to do so. However as I mentioned in the ground rules up front we don't want to focus, this is not a discussion on any particular treatment, the

virtues of it except to see what we can build upon to understand that common ground of drug development. What type of symptoms can treatments address? How meaningful that would be to you? And how you know those differences both in terms of frequency, how many more times you experience desire for example, as well as I'm going to call it the quality of that desire or that arousal; the strength of it or the intensity of it.

So as you think about your comments today try to build in those things. Please don't focus on specific treatments just for the sake of that treatment.

I'm also going to ask again when you are giving your first, when it is your first time speaking in this topic as well to always state your name and also disclose if you are associated with an organization that has and interest in FSD, if your travel has been sponsored, or if you have significant financial interest in drug development for FSD otherwise.

So we have four panelists up front.

Again very similar to what we went through this morning. We are going to listen to these experiences shared. And then we will move into the facilitated discussion on this Topic.

So without further adieu we will ask Judith to begin. And you just push your little red microphone and bring that microphone pretty close so we can hear.

Thank you very much.

JUDITH: First of all I'd like again to thank Veritas for our travel arrangements. I'd like to thank Sara for telling me to change good afternoon to good -- I mean good morning to good afternoon in my introduction. And I'm not affiliated with any other pharmaceutical company or drug company.

So my name is Judith. I'm 66 years old and I've been dealing with FSD on and off for 17 years. I would like to thank the FDA for their interest in the unmet needs of women. These are exclusively my own thoughts on the subject.

I believe I am entitled to and deserving

of a meaningful sexual relationship as are my daughter- in-laws and granddaughters. It is not solely the woman who is affected by this disorder, but her spouse, children, plus people in her social circles and workplace.

I'm a breast cancer survivor. I was on HRT when diagnosed in 1996, electively put myself back on HRT after a radiation treatment in '97. When the symptoms became a quality of life issue in 2009 I was diagnosed again with breast cancer a second time, taken off HRT before a double mastectomy in 2010. Within three months the great sex life I had previously enjoyed was gone.

I felt anger, cheated when it became apparent that it had disappeared. Symptoms I experiences which had the most negative impact on my life were fatigue, vaginal dryness and painful intercourse. These symptoms continuously awaken me which meant I averaged 45 minutes of sleep a night. I was exhausted. I did not have the energy for intercourse or for anything else. I became irritable. I didn't like living with

myself, never mind how difficult it was for my husband. Mood swings were crazy. I was short tempered, not pleasant to be around contrary to my normal behavior which was upbeat and positive. My libido was low. I knew I wanted to have sex but I had no desire. I refrained. However I love my husband and wanted the closeness, the feeling of well being that comes with the passionate satisfying sexual relationship. My self confidence plummeted. I felt I was less of a woman as I no longer had the sexual appetite that I had previously experienced and enjoyed. I had no desire. It had completely vanished. The vaginal dryness was uncomfortable, penetration was painful and stressful. Having sex was not at all appealing. The pain during intercourse was excruciating. Both my desire and interest were overshadowed by my fear of pain.

My husband introduced me to Dr. Goldstein who he had met at the VA. Diagnosis was made after an initial interview, a series of blood tests, questionnaires and a vaginal tour. I was

told that my clitoris was that of a six year old and that my hormone levels were almost non-existent.

Here was a doctor who believes in something other than verbal therapy, something tangible, a plan that hopefully would restore my lost sex life. Treatment has been an ongoing process for the last two and a half years. Initially changes in my symptoms would fluctuate from week to week, then month to month depending upon on regulation of my topical medications. I still record topical levels daily. Under Dr. Goldstein's strict monitoring blood tests were initially done every three to four weeks, now every eight to 12.

My fatigue is gone as well as the vaginal dryness. I produce sufficient lubrication, desire has increased and intercourse is no longer painful. I once again experience both vaginal, clitoral orgasms. However my desire is still not up to previous levels.

Getting the physical body in order was

paramount. Menopause and the aging process still manage to affect both my interest and desires, so therefore ongoing treatment is necessary.

I tried various medications until we found which worked best. Currently I am on DHEA, Progesterone, Estradiol and Testosterone Versabase, Estrogel and Testim.

I've had sessions with the sex and physical therapist. I did need to adjust the Testosterone dosage when acne worsened. Monitoring my blood test was followed by adjustments made to the Estrogel insuring my count stayed within the required range with someone with my history of breast cancer.

Downsides are the costs of the treatments not covered by insurance or Medicare, acne, some increasing facial and body hair. I believe treatments that deal specifically with women's low hormone levels and sexual dysfunction are crucial to our psychological and physical well being.

FDA approved medicines that can target

improve and enhance women's sexual function plus be cost effective would be awesome.

I personally as well as all other women need the FDA's help in finding a solution to FSD. Thank you.

DR. EGGERS: Thank you very much.

And now we will go to Katherine.

KATHERINE: Hi, I'm Katherine. I'm from Indianapolis, Indiana. I need to thank Veritas Meetings who was given grant by SPROUT among others for covering my basic travel expenses and making it possible for me to be here today.

I learned in high school sex Ed that a woman's sexual prime, so to speak, is in her 30s. Yet here I am age 30 and I have no sexual desire whatsoever. Things were very different in my 20s. I had an extremely healthy sexual appetite and a great relationship with my husband.

Immediately following the birth of my first son I noticed that I had not a lack of but no libido. Still I gave it time thinking well maybe it is just because you had a baby and you

are still healing. I actually waited a year and a half before finally booking an appointment with my family doctor at the request of my husband.

I told my doctor I need something for low libido. What do you have for me? His reply there isn't anything for women with sexual dysfunction but we can put you on an anti-depressant in hopes that being in a generally better mood will help with your libido.

[Huge sigh] so I left the office a bit confused. Why wasn't anything available to help me? Is it because I am the only woman in the world dealing with this problem. Surely I must be missing something. I began taking Celexa regularly and saw no improvement. My mood was happy, yes, but I was happily not wanting sex.

[Laughter.]

I went off of Celexa after three or four months of usage. I didn't have any negative side effects. But if I was only using it to help with my libido and it wasn't working I had no need for it anymore.

I looked at other areas of my life. Could stress be an issue? Maybe my diet, my weight, depression; no because I eat organic fruits and vegetables, I maintain a healthy BMI, I exercise four to five days a week, I live a low stress lifestyle and I am not depressed. I am actually quite the opposite. The only thing to fix in my life is my low libido which is negatively impacting my marriage.

So I feel like my body has let me down. I feel like it is out of my control at this point. And I feel like I pulled a bait and switch with my poor husband who is undoubtedly wondering where the old me has run off to.

If there were a treatment available for my problem I highly doubt I would care about the side effect of the drug, the pros would far outweigh the cons in this situation.

The old me is what I'm after. I want to joke and laugh and flirt. I want to think about sex. I want to initiate sex. I want to have more of it. I want to be the woman my husband married

not too long ago.

Thank you.

DR. EGGERS: Thank you very much Katherine.

And next we'll go to Barbara.

BARBARA: Okay. I also want to thank Veritas for supplying the grant so that I could be here to speak to all of you. Although I don't care how much it cost me, I'd be here to speak to all of you believe me.

Around 25 years ago I noticed that my sexual desire was decreasing. Within a year it was gone altogether. I felt dead inside. And although I had a wonderful marriage and love my husband very much I have no desire for sex. I felt shame and guilt. And had no idea what was happening. On the rare occasion that we did have sex it was done out of obligation rather than desire. I was embarrassed and reluctant to talk to anyone about it.

When I finally summoned the courage to talk to my gynecologist about it he listened but

said he has no solutions to offer. I researched this on my own and found that some people were using Testosterone cream. I was able to try Testosterone cream and after several months there was no change in desire. The only noticeable physical change was significant unwanted hair growth. So I discontinued the cream shortly thereafter.

In 2011 I answered an ad for women experiencing low sexual desire. After being evaluated I was diagnosed with HSDD and enrolled in a double blind study conducted by Dr. Irwin Goldstein for a drug Flibanserin. Initially I had no change whatsoever in desire. After a few months I was informed that I had been on the placebo and was asked if I would like to try the real thing. I said yes. I couldn't say it loud enough. And within a couple of weeks my feelings had changed dramatically. I had sexual feelings which I had not felt in many, many years. I was the one initiating sex much to the surprise of my husband and the experiences were very pleasurable.

I also had no negative side effects.

Shortly thereafter Dr. Goldstein informed me that the drug had been pulled and the trials discontinued. I was devastated to say the least.

After 25 years I had found something that worked and then it was taken away. Without Flibanserin as an option Dr. Goldstein tried a Testosterone pellet, off label, which was inserted via a minor surgical procedure. This caused the same unwanted hair growth and now weight gain but no change in desire to speak of. Had this worked I would have consented to undergo this minor surgery every six months or however long it took. But it did not work.

One benefit of this experience is that I am no longer afraid to talk about my condition with friends and family. It is amazing how many women of all ages I talk to that have some degree of HSDD and have been quietly seeking a solution.

My husband and I are closer than ever now that he understands what HSDD is and how its

affects have nothing to do with my feelings toward him.

I conclude, I'm a nurse, I teach at three local hospitals, I deal with many doctors. Since 2011 I have been talking about HSDD to the doctors taking my classes. So many have patients with HSDD and after hearing my experiences they are extremely interested in having a viable solution for them.

I would like to see the FDA approve a treatment so women like men can have a solution for their most common form of sexual dysfunction and not have to go off label or order who knows what from foreign countries.

This disorder is real. And we need a solution.

Thank you.

DR. EGGERS: Thank you very much.

And finally we have Susan.

SUSAN: Hi. I'm Susan. I am not affiliated with any organization who has paid for my trip here today. But I did contact the New

View Campaign this summer as a way to get my story out. And I heard about this meeting through the New View Campaign. And I don't think I would have heard about this meeting if I hadn't made that call.

I'm not currently engaged in the medical world around my condition. So I don't think I would have known about this meeting.

I stopped having desire for sex about two years into my now eleven year partnership with my husband. Although I was alarmed it wasn't until about four years later when I lost my orgasm that my attention was capture.

Up to this point I had a very narrow view of sexual desire focusing mainly on physicality. I really thought I had lost something. I was resigned to the idea that sex was going to be a drag for the rest of my life. As I began my process I went down some of the common paths of pathology, testing hormones, looking in the DSM, et cetera. My doctor told me that my Testosterone was on the low side of normal

and that I could try experimenting with hormones. I told her I was working on relationship and that I wanted to try that first and not confuse drug therapy with relationship work. She stated she thought that was best; that I could try hormones down the road if I wanted to.

Once I decided I didn't want to live a sexually repressed life I started finding information that would be helpful to me. I picked up an old book by David Schnarch called Passionate Marriage that I had laying around. The book helped me to expand on my curiosity and explore my orientation towards sex and desire and find better questions. What is desire? Maybe it is not about a physical feeling. Maybe it is about something entirely different that exists outside the physical realm.

My partner and I had done work on ourselves in a therapeutic setting challenging individual issues that worked against us in relationship. We exposed a war between us sexually that had to do with the stereotypical

ideas about men and women that we had personalized to each other. We would bring these ideas to the sexual relationship without verbalizing them thus creating distance and disconnection. We learned through our study of the work by David Schnarch that our sexual problems were a co-created problem in our relationship and that I wasn't the problem. Schnarch's approach helped changed our thinking from pathological to relational.

Once I was able to move out of feeling bad about my waning physical desire I relaxed and started a powerful process of learning more deeply about love. I didn't recover physically desirous feeling prior to sex. I had originally thought this was the goal. I was wrong. What I do have is a deep desire for a relationship and that is what drives my desire to be sexual with my husband.

The physical experience changed for both of us. Our kiss became connected and deep. My orgasm came back with a quality I hadn't experienced before. Most importantly we now know

sex is relationship and we enjoy the physical contact as a way to interact and be close and connected on a deep intimate level.

My partner and I differ in our physical experience of sex. But that is no longer threatening to either of us. Accepting our sexual differences has been part of the whole change.

Today when we have problems that arise sexually, instead of looking for something outside the relationship for help, we go to what is going on in our life right now that could be affecting us.

My therapist said that whatever is going on in the kitchen is going on in the bedroom.

When I think about the downsides to my journey we both were challenged along the way to stay with it. The material that arises is unpredictable and where you are headed is unknown. What kept me going was the immediate and projected and far reaching benefits.

It literally changed the way we live, share space, and relate together on a daily basis.

What I would look for in an ideal treatment for my lack of desire is a broader definition of normal sexuality for both sexes. I would appreciate a movement away from a culturally driven definition of normal that creates distress and anxiety in people when they don't think they are living up to an ideal.

I think there are all kinds of reasons people don't relax sexually in their relationships and it is much more complex than physical diagnosis and physical treatments.

It is my personal opinion that treatments that allow for sexual difference account for the human waxing and waning of physical and sexual desire and arousal and focus on relationship work in general would be most helpful.

Where to go from there is more a question for each person than it is finding an answer for all. I feel grateful that there was no shortcut for me. I would never have evolved my consciousness to embrace this much more important

understanding of life and love in relationship.

And the work continues.

Thank you.

MS. EGGERS: Thank you very much.

I think I'll save clarifying questions until we get into the discussion given the time.

It goes without saying that we owe another round of applause to these women who have so eloquently shared their experiences.

[Applause.]

They have been -- they really set I think a good foundation for our discussion.

Again I am going to ask another show of hands. How many of you heard your experiences reflected in at least one of the panel comments, one of the panelists?

Okay.

Anyone whose experience differs completely from what you heard?

Okay. So it sounds like we've captured generally a sense of the range of experiences that we've had; both the successes and the failures

with treatments and the wide range of perspectives.

We are going to start with a polling question that will set the stage to understand what you here in the room and what you on the Web have tried or are currently doing. So I guess we are only focusing on what you are currently doing.

So what are you currently doing to treat your condition or its symptoms? And this is a long list, so I'll read it out for you. You can select all that apply. So if you've got your little clickers, please use them. Any prescription medications and for that let's include investigational therapies. Over- the-counter products. And by investigational if you've participated in a clinical trial for a therapy.

b) Over-the-counter products, c) physical therapy, massage or acupuncture, d) dietary supplement or dietary changes, e) lifestyle changes such as exercises, avoiding stressful situations, et cetera, behavioral

therapies or couple sex therapy, some other support group would be g). h) If you are doing something else that you don't think fits into one of these categories. Or i) if you are not doing or taking any therapies of any kind. And you can select all that apply.

Yes, it is unsurprising that we get a range of many different things. The most prevalent here in the room being the prescription medicines followed closely by the over-the-counter products. We will get into that a little bit. A quarter or you in the room say you are not doing or taking any therapies which is interesting. We might follow up on that a little bit and get your reasons why for that.

On the Web?

MS. GIAMBONE: On the Web we have about 50 percent of the people not doing or taking any therapies. And --

DR. EGGERS: I'm sorry, 50 percent?

MS. GIAMBONE: Yes. Just about 50 percent. And then we also have about 36 percent

incorporated lifestyle changes or are using over-the-counter products.

DR. EGGERS: Okay. Thank you. So we have a lot to cover. Again what we are looking for is really how these overall are changing in how you feel symptoms. And in how they are addressing your overall need for therapies of any kind.

MS. WHITTAKER: Excuse me, Sara, can we ask for clarification on the Web as to how many patients are taking prescription?

DR. EGGERS: Yeah, how many are taking prescription?

MS. GIAMBONE: We had 18 percent taking prescription medication.

DR. EGGERS: Okay. So we will begin with medical treatments, medical therapies. And we are actually going to start with investigational drugs. Barbara mentioned and investigational drug, Flibanserin. And we are wondering -- first of all how many of you here have taken an investigational drug, Flibanserin or

anything else that would like to share your experience with that?

Okay. Here.

So what we are really interested in again is what noticeable changes are you feeling and what and how do you know that those -- how you know that those changed, what you perceived differently and how meaningful those are to you.

AMANDA: I was on the Flibanserin trial but -- I'm Amanda. I'm sorry. As you know the trial was stopped. I also had tried Testosterone before that off-label. Unfortunately I found that worked better in the gym for me than it did in the bedroom. But when I was on Flibanserin it did not take long, much like Barbara's experience. It took a few weeks before I noticed a dramatic difference. Going from no thoughts during the day and really no desire, no initiation to suddenly texting and earlier when we were talking about visual clues and written things I always say it was like I'd text him in the middle of the day and get a flutter and I did not mean in my heart, in

the middle of the day for no apparent reason and frequently we would opt to skip dessert at dinner and go home. So I noticed an initial change very early on. I would say I began initiating where I had not in a long time. And likewise virtually no side affects whatsoever. So I was also devastated when that trial ended.

DR. EGGER: Any other comments? We are going to talk about Testosterone and other hormone products in a little bit. Any other -- one other investigational drug, a trial that you were in to demonstrate how you saw changes in symptoms or did not?

Okay. We have one in the back. We'll get a microphone to you.

MS. GUESS: Hi, I'm Marsha Guess. I am actually a physician who treats sexual dysfunction in some women. If you could just expand on your response and how long you used the therapy and how long you responded to the therapy and whether or not your symptoms changed while you were taking that therapy?

DR. EGGERS: Thank you very much. As we go through I think those are great follow up questions as we go through any of these therapies to address.

So if there are no more comments. Let's move to Testosterone products because we heard two of you on the panel discuss those. And several of you had mentioned it this morning. There are different types of Testosterone products. So I'm going to ask for some help on a show of hands just to see what the different types that we have.

Christy can I put you on the -- a show of hands please for --

DR. CHANG: A topical Testosterone, cream, gel?

So let's start with FDA approved topical products.

DR. EGGERS: For men?

DR. CHANG: Yeah, for men?

DR. EGGERS: That are used off-label?

DR. CHANG: What about for a compounded Testosterone product?

DR. EGGERS: If you have used -- if you are using it now or have used it?

DR. CHANG: Injections, Testosterone injections?

Testosterone pellets?

DR. EGGERS: Okay. So we have the wide -- we run the gamut in terms of experience with the Testosterone products. We won't differentiate for the rest of our conversation but we will just take note that there is a wide variation.

Would anyone like to follow up? We heard I'm going to say more successful and less successful experience up here. Would anyone like to follow up first with who feels that they are finding success with their Testosterone product and do you want to explain that?

MS. ROBSON: I am Michelle King Robson, excuse me, and I have not been paid to be here today.

I suffered from a complete hysterectomy at the age of 42 and tanked. So my hormone levels were gone. And it took me a year and nine doctors

to figure out how to get well. And there were two things, one was estrogen, Estradiol and the other was Testosterone cream. With those two things it changed my life. And it actually caused me to start a company called EmpowHER.com which is women's health online because I almost didn't survive it.

One of the things, one of the side effects that I had along with suffering from sexual dysfunction was I had no brain function. My short term memory was gone, I had joint pain, I had sleeplessness, all the things that women have talked about today; hot flashes, night sweats, you name it.

This is so common on our sight. It is so disturbing to see what women are faced with every single day and we've got to make changes here. And I am so happy that we are doing this today.

DR. EGGERS: Anyone else over there.

CARMON: Hi, I talked a little bit earlier but I didn't tell you that I've been

married to my husband for 33 years and we have ten children together and yes we do know what causes that.

[Laughter.]

And I didn't enjoy it for about 30 years of our marriage. And I am so thankful that we went and had blood tests done and found -- I was grateful to find out that my Testosterone was in the basement. And I am using a product called Axiron which is topical and I put it on under my arm. And it has helped me tremendously. I had not been having orgasms for a long, long time. And I not only can have an orgasm now but I can have multiple orgasms during a sexual encounter with my husband which makes him really happy. It makes me happy.

So I am very thankful for that. And one thing my husband has said about using these products to help you when you are having problems with -- I was diagnosed with Hypoactive Sexual Disorder. And one thing that is a good way to think about it is that people have hearing aids,

they have eye glasses to help them when they are vision isn't good. And to treat this like it is some oddity; that it is something we shouldn't look at as another tool that we can have is wrong. It is just another tool in our toolbox and we can use therapy when we have problems. And yeah, I was a busy mom and needed to get more sleep. But the problem was actually physical with me. It wasn't a mental problem.

So let's give women another tool that they can use to help enhance their ability to have a better sexual life with their husband or their partner.

DR. EGGERS: Thank you.

Carmon, right?

CARMON: Yes.

DR. EGGERS: Can I ask a follow up question. When did you first notice changes after taking the Testosterone?

CARMON: It was within weeks.

DR. EGGERS: Okay.

CARMON: And it has been very steady and

it has been a lot better. It is very noticeable.

DR. EGGERS: Thank you.

Are there any on the other -- oh, go ahead.

BEVERLY: Hi, you probably know who I am. So --

DR. EGGERS: Beverly.

BEVERLY: My name is Beverly. I have experience with at least four or five of these medications. So I thought it might be beneficial to tell you I started with Testim, topical medication prescribed for men. Unfortunately I had to use so much of it that I smelled like a guy and my girlfriends were attracted to me which really wasn't appealing.

[Laughter.]

That one had to go because it didn't do anything to help my boyfriend be attracted to me; right. So we switched to Axiron under the arm, great medication. Felt the effects, major stomach upset, had to go off of that one.

Then I went to Testosterone injections

in my thighs and I learned to self inject. Fascinating process, lots of bruising, lots of bleeding, lots of drama but it worked. Unfortunately I have an idiosyncratic body that metabolizes medication very quickly, so I went from once a week, to twice a week, and I said this isn't working anymore.

Finally I said all right fine, the pellet, we'll try that. It is a beautiful thing. It lasts a long time. It is minor in putting it in but that is the one I've stuck with.

I just thought it might be beneficial to hear all of those different medications that are approved for men but not for women but that I've tried. And honestly because I process medication so quickly I could feel a difference within a very short period of time, like a week. So hopefully that helps.

DR. EGGERS: Thank you very much.

Okay. One more to see someone who has an opposite experience where it hasn't worked for them or that the side effects were such that or

the downsides were such that you choose to not take the product anymore? Oh right, there, yep.

KELLY: I'm Kelly and I have done compounded Testosterone and then Testim as well and I didn't see any effect whatsoever. And at that point in time and I didn't even see effect in the gym, like that other lady. I was at least hoping to get something out of it. But at that point in time stopped using that one and then I had also been prescribed Wellbutrin at the beginning to see if that would maybe help me at least enjoy life. And it probably made me kinder to my children but it still didn't give me any better desire. My children thought that I was a nicer mommy at that point in time. But no Testosterone treatment has worked for me as far as those were concerned. And like -- they smell and they are sticky and you think does it -- can it really make a difference and for me it didn't. So right now I am not doing anything. It has just kind of stayed the same.

DR. EGGERS: Okay. Yeah, go ahead.

DR. KWEDER: A couple of the folks, I just want to ask you a specific question because a couple of folks who have described success with Testosterone commented on having had their Testosterone blood levels checked.

KELLY: Yes.

DR. KWEDER: Were you diagnosed with low Testosterone?

KELLY: Yes, I was.

DR. KWEDER: Thanks.

DR. EGGERS: I want to make sure that we keep moving on here. So I'm going to move to other hormonal products that aren't Testosterone. We heard some other mentions of those up here; if anyone would like to share your experiences with any of the other hormone products? Okay. In the back there.

MEG: Hi, my name is Meg and yes, Veritas paid for me to come here. I had a hysterectomy; did keep my ovaries. And have once the menopause symptoms started coming on I started taking HRT, a patch. And I can tell an amazing

difference in not only sexual responsiveness but in other areas of my life when I take it and you know the doctors are all like you can only take it for a few years. They are very interested in me weaning off of it for whatever the side effects are. And I am very concerned about what am I going to do when they say that those years are up because I mean that affects all areas of my life including my -- at work how well I can perform. I get the brain fog. I start crying, which I never cry at work. I mean because I have 50 employees and you know you can't cry in front of 50 employees. So I am very very concerned that what is there, what is on the horizon, not just for sexual responsiveness but for the other areas in our lives because I mean I am a baby boomer. We are all working longer and longer. Women have these issues and there needs to be some kinds of solutions because we are productive way into our years that in the past you would have been retired. So that is definitely something that I'm interested in and needs to be addressed.

DR. EGGERS: Thank you for sharing that prospective, thank you.

Let's move on, there was quite a few of you who talked about over-the-counter products. By the way if we are not getting to the products that you take, please submit those to the Docket or if we can - - maybe we will have some time at the end. But I want to make sure we touch upon some of these. Do you have a comment sir?

UNIDENTIFIED PERSON: Can you talk about PDE-5 inhibitors.

DR. EGGERS: Can we -- PDE-5 inhibitors?

Okay. Can we have a show of hands? How many have taken those off-label? Viagra.

Okay. Maybe you could clarify the question for me please.

DR. CHANG: PDE-5 inhibitors are medications like Viagra, Cialis, similar medications.

DR. EGGERS: Okay. Show of hands. So a number of you have.

Yeah.

KAREN: One of the physicians I was seeing recommended that I try Viagra. So I got a very tiny prescription and I tired one pill and the only thing that got swollen were my sinuses and that was it.

[Laughter.]

DR. EGGERS: Well we -- we will take one more.

DR. PARISH: Yes, Sharon Parish from ISSWSH. Just backing up I'd encourage you and urge you to separate the comments of naturally and surgically menopausal women about their treatments from those that are pre menopausal because their experience of hormonal treatments may be very different. And it will confuse the understanding of the patient experience if that is not separated more clearly as we go forward.

DR. EGGERS: Great. Okay.

So maybe as we do go forward if you feel comfortable saying at what side of the change you are on, that would be helpful for us. And then if you are writing in to expand on your experience in

the Docket if you could similarly let us know that.

As far as the over-the-counter products we don't want to spend too much time but I think it would be useful to understand what you're including in this. So would anyone like to just briefly mention what they included in b) when they indicated it?

LOUANNE: My name is Louanne, I spoke before.

Lubricants obviously, so liquid silk is our favorite but I think the use of a lubricant isn't necessarily a thing that is associated with sexual problems. Some people use it just to enhance pleasure as a starting point even when they are 20 and have plenty of their own natural lubrication to go around. Sexual toys and accessories I guess would perhaps fall into that category too.

DR. EGGERS: Anyone who did not include lubricant?

Okay. Right here.

CHERYL: Hi, my name is Cheryl and I have tried over-the-counter Provestra and Steel Libido. None have worked for me.

DR. EGGERS: We will go to Amanda.

AMANDA: I'm Amanda and likewise I did actually order something off the Internet one time. I don't even remember the name of it, that is how sad it is but promised increased libido. That did not work. And my comment about lubricants; they are great as far as physically helping the process but they do nothing for helping your desire.

DR. EGGERS: Okay. I see some heads nodding to that.

Let's talk about I'm going to put lifestyle changes and behavioral therapies or couples sex therapies and support groups kind of together as things that work on relationships and other things. And we did hear Susan explain that and others have today.

Does anyone have an experience with that that is different than what we've already heard

that can expand upon this, like to talk about it?

If it has worked for you or hasn't worked for you?

Yes.

JENA: It is not like a support group. Sorry my name is Jena Umbidwa (ph) and I don't have any financial interest or affiliations.

What I found useful was reading about my sexuality because I had the view that I have to have penetration and achieve orgasm through penetration. And it was very stressing for me because this was not the case. And then I started reading about my anatomy and about women's pleasure centers and I read Hite report from Shere Hite and she was pointing out that a lot of women participating in her research were not achieving orgasm through vagina orgasm through penetration. And then I started to problematize that real and also I watched Orgasm Inc. which you should definitely watch it is very informative. Then I started thinking about my sexuality and I found how I can achieve pleasure and this was not the

way that I was learned before that we see in the movies or that is teached to us. So I had this increased knowledge which was reliable. It was a great knowledge and as Mary from the former interview stated it was knowledge from Internet or movies or I don't know other stuff. And I think it has changed my conceptualization of sexuality and my experiences a lot.

DR. EGGERS: Jena. Thank you.

We will have Sandy follow up.

DR. KWEDER: There actually is an FDA approved medical device name of which is escaping me at the moment. Yes, I want to know if anybody -- that isn't one of the choices up there and I'd like to know if folks have had experience with that.

DR. EGGERS: Sure. Can we have a show of hand if you have currently or have tried using that device? EROS.

DR. KWEDER: I believe it is for sexual arousal disorder and orgasmia. I believe that is the indication.

CAROL: EROS is a device and it is a device to encourage arousal in the vulva and the clitoris and it used to be by prescription only. I don't know if it still is. And it used to cost around $500. And if you look at their Website and you look at the shape of this device it is very much like a vibrator, different kind of vibrator.

DR. EGGERS: Any other follow up questions on medical treatments?

Oh, okay, we've --

MR. SHIELDS: Thank you. My name is Wayne Shields. I represent an association of health professionals, Association of Reproductive Health Professionals. The reason I'm commenting is not for a medical issue. It is reporting back what my folks tell me that they experience on the front line. My folks are basically the ones who work with clients. And what I hear back from them and I hear this a lot is that there isn't adequate response for this issue with their clients and that there is indeed a subgroup of clients who simply need help with desire, the desire side of

the equation. I agree with some of the folks earlier who mentioned that it is complicated and different for every individual and that is true. But there is definitely a reported group of folks who no matter what have trouble with the desire side of the equation. So I'd encourage us to pay attention to that group even if they are not the majority.

DR. EGGERS: Okay.

NATALIE: Hi, this is Natalie again. I wanted to make a comment about --

DR. EGGERS: Can you hold the microphone closer.

NATALLIE: -- about physical therapy, massage and acupuncture and so forth. I had a -- like I mentioned before a great sex life with my partner. I didn't change anything. I had an IUD put in, took it out six weeks later. One month later he was on a trip, he got back and it was like a switch that went off. Everything was all of a sudden different. And I went to about ten doctors, hospitals, institutions and everyone said

it was in my head. I throughout that year tried -- we went to couples therapy. We went to sex therapy. I had physical therapy which was very invasive. Acupuncture. I even had a guy go in and do hysteroscopy and laparoscopy to see if he could see anything in the camera that was wrong with me. And it was perfectly normal. And I can talk about how it affected me and how depressed I was and how mal- functional and just horrible it was.

But I finally find, I was doing research, a book that got published two months earlier and that is how I found my doctor and he took the hormonal tests and found that I had only 20 percent of what was normal for my age group of Testosterone. And literally a week or two after I was treated everything changed and I was fine again.

So I just wanted to reiterate that everything else I tried didn't work.

DR. EGGERS: Thank you very much.

Are there any Web comments on treatments

particularly those we haven't had a chance to discuss yet?

MS. GIAMBONE: We heard several treatment options that did not work for some of these participants including BioTE pellet therapy, Testim. In terms of lifestyle changes, meditation did not work. And another participant commented that she was prescribed an anti-depressant and that made her unable to reach orgasm.

DR. EGGERS: Thank you.

We talked earlier in the afternoon about tracking condition as it changes over time. And there was a lot of difficulty in answering that question because it depends if you are on treatment, if the treatment has natural cycles and everything. And so I think it is useful to follow up on that question again. I am going to pose a side experiment if you went to your doctor and he or she said I am going to start you on this new therapy, whatever therapy you are taking and I want you to track your symptoms given the therapies that you are currently taking are there

variability in those symptoms and please when you are answering the question state which therapy you are on or the combination. But are you noticing changes over time in those therapies as you are on treatment. And if so, if you were asked to identify those treatments over time what time period would you need to use: day, weeks, months, in order to kind of capture that variability as it changes. Hopefully that question made some sense. Any brave souls to try to first answer the question as I posed it?

Okay. And then we will go --

MS. ROBSON: Michelle King Robson. I go every three months for testing so I do blood work. And it does change so I've been on Hormone Replacement Therapy, the Climara Patch specifically and then I take Testosterone twice a day that is compounded, 1/8th of a teaspoon in the morning and afternoon to keep the consistency and flow the same because a lot of women go like this with their treatment therapies.

We test every three months so we do it

by symptom and also by blood work. So she wants to know both because sometimes the blood work can be normal but you are still having some of the symptoms. If I gain a little bit of weight it can change. If I lose a little bit of weight it can change. It really isn't a one size fits all program unfortunately. It is more dependent upon each individual woman as to what they need and what they are going to end up taking.

So a lot of it -- it has changed over time, over the past 10, 11 years it is constantly changing and being tweaked. And that is how I stay well and healthy.

DR. EGGERS: And that longer time period that you are talking about you are talking three month time period that you revisit do you track in between those three months?

MS. ROBSON: I am always tracking.

DR. EGGERS: Okay.

MS. ROBSON: Yeah. You have to, I mean you really do.

DR. EGGERS: Anyone else. I'm sorry

hands went up and I -- we'll go to Sue.

MS. WHITTAKER: Can we just go a little bit farther. When you said you are always tracking, how often do you track? And what are you tracking?

MS. ROBSON: So I have to track on a daily basis because my medication changes up. One day I'll take one patch, the next day I'll take a different dosage. So it has to be tracked on a daily basis because of the differential in it; right, so and the same with the Testosterone Cream too. So everyday there is a tracking system on my phone actually and I always know when I've forgotten to take something because I will definitely have a side effect or a symptom from it. It is almost immediate. You get to know your body so well.

DR. EGGERS: And what type of effects are you tracking when you are -- are you writing down certain symptoms?

MS. ROBSON: Yes. I'll write down -- so for example I had heart palpitations and without

getting into great detail of it I went into -- because having heart palpitations and being 55 years old isn't really a good thing since heart disease is the number one killer of women as we know. I wasn't getting enough estrogen. So when I went into the physician, when I went into the cardiologist they wanted me to take less. They wanted me to go off the estrogen. And then when I went to my primary care physician who is taking care of me she said you need a little bit more. And it actually worked the heart palpitations were gone.

Same with joint pain. So joint pain traveled in my body. So if I didn't take the right -- if I wasn't taking the right amount I'd get joint pain.

Same with sexual function, libido and brain function. Those are all pretty typical.

DR. EGGERS: Thank you.

We had a comment over here.

SUE: So I'm on a different Testosterone. I am on the pellet. Sue. And the

pellet last approximately six months. But it is individual with each person whether you are a man, whether you are a woman. I mean I think we have a lot more similarities with men than people think about. The Testosterone for me takes four to six weeks to kick in and then the last three to four weeks of that six month period it is pretty much gone. So I can tell by my symptomatology I know that if I have symptoms right after the pellet is put in that they are going to go away. On the other end I don't recognize the symptoms until my HSDD has returned for a few weeks. So for me while I don't track it on a piece of paper it is about a three to four week recall at which point I realize oh, I need a new pellet. I would never -- on a daily basis I don't think about it but I'll think back and go oh, I've been thinking a lot about sex lately, I guess the pellet has finally kicked in. It really takes a little longer for recall for myself personally.

DR. EGGERS: Okay.

We have Amanda.

AMANDA: Amanda. When -- I agree with what she was saying. I still think it is not it for me. I was not a daily process. I don't need to think about it every day. I'm busy. I'm a wife. I'm a mother. I work full time. I can't take the time to think is my level low or I'm going to have to go have something replaced. When I was on the Flibanserin trial we had to fill out a daily diary which was almost comical because quite honestly like I said I'm a mother, I work full time, I don't think about sex 24/7; that is not what it is intended to do. But it is the lack of desire doesn't just go away one day and you take a pill and it returns. I personally don't believe this is a condition that is just going to get better and then you quit. I think it is something that we are going to live with; it is a long term process, it is not a daily tracking. It is more of a weeks and months and future and everything. So it is not like physically you can take it one day and it turns on and you don't have to take it the next day. It is either on or off.

DR. EGGERS: Thank you.

So I want to ask a question about -- we've talked about symptoms and changing over time and there are two concepts. There is the number of times that you might think of something or that something might happen. And then there is the intensity of that or the strength of it or the quality of it, however you think of it. When you are on these treatments and you are talking about how they affect you, are you thinking about both of those or does one come to mind more the number of them or how do you conceptualize that difference when you are thinking about how well treatments work for you between the number of times, maybe a frequency, with which something returns or the intensity with which it returns?

So when you are thinking about how well treatments are working for you how do you conceptualize the difference between the number of times so that you think more often about something or you that you experience something with more intensity, maybe arousal with more intensity? Do

you conceptualize that differently?

BEVERLY: It is an interesting question. I heard Sue say her pellets last about six months. Sometimes mine last two months, sometimes they last four months. And I feel the effect right away. So my body just metabolizes it differently than hers. But about three weeks in to four weeks into the pellet I think my Testosterone level goes so high that I think about nothing but sex. I wake up every day thinking about sex. I go to bed every night thinking about sex. And like, okay, really I would like a therapy that worked better, that was more even for me because I end up becoming obsessed with this conversation.

[Laughter.]

Right. So I go from not being interested at all to not being able to think about anything but that. But then about three weeks later I'm not thinking about it at all and I am like what happened to me? So the rise and fall is definitely more profound for me. And no I don't keep a diary. I have a clear, very clear recollection of when it starts

and when it stops. But hopefully that helps.

DR. EGGERS: Karen? We will go with Karen here next.

KAREN: I observe that there's a lot of variation in this one particular product that is being used. It is my understanding that it is off-label for women; is that correct?

DR. EGGERS: You are talking Testosterone?

KAREN: Testosterone, whatever. It is off- label for women.

DR. KWEDER: Yes.

KAREN: I just observe how interesting it is that all these women have such a different experience with this product that is not FDA recommended for women, approved.

DR. EGGERS: Your point has been noted.

So we only have -- Oh, go ahead Hylton.

MR. JOFFE: I had one question. I was interested in hearing perspectives. It sounds like with treatment such as Testosterone you are talking about something that we take every day.

And I was wondering what folks thought about intermittent treatments where you see this as a condition where you take something when you want to feel more desire as opposed to something you take every day? Does that make sense to anybody? I'd be interested in hearing thoughts on that.

DR. EGGERS: We'll go there first.

LOUANNE: My name is Louanne. It is funny you asked that because I was just having a thought does this comment fit anywhere in this discussion. I've been using Testim on my calves for 12 years. And I just put a little bit on and rub my calves together while I'm brushing my teeth every morning and that is sort of a two for one kind of thing; that is how I remember to do it every day. And then about this time a year ago my husband was diagnosed with tongue cancer and so here was a big change in our life and lots of surgeries and things changed. And so sex was not on our list of activities for a while. So I just backed off on my Testim which was under my control and I just let it ride until he was feeling back

to a bit of a more normal interest in sexual things. So that is what I think you are asking as life fluctuates can you adjust your treatments and I have. Is that what you are asking?

MR. JOFFE: And even one step further intimately using medications from one week to the next or one day to the next, using or not using. Interested if that resonates with anyone or makes sense to anybody?

LOUANNE: If I know we are going on vacation to Hawaii I'm usually gearing up the week before. Yeah.

[Laughter]

One year ago. So yeah in anticipation because Testosterone isn't sort of like you put it on this morning and tonight you feel like wow it is a kicking in thing. For many people it is like a two month process if they are particularly low. For people who kind of just want to ride the top of the wave for whom it works I think they can kind of pull back and forth on the throttle a little bit based on what their plans are and what

their life is like. But I think that what someone over here said. It was Karen I think. I think that there are two probable causes to sexual desire problems. Some of them have to do with Testosterone and some of them have to do with something else completely going on the brain that is different. When people don't get Testosterone to work I think it is a whole different diagnosis.

And frankly I was really upset when I saw DSM5 put arousal and interest in the same bullet. I was like what are they thinking about. This is crazy because they are two very different processes. So that was my take as a therapist and a patient. Did that answer your question?

DR. EGGERS: We will go with Katherine. Katherine do you have an answer for this question?

KATHERINE: I think so. What I was going to say was my sexual dysfunction isn't a physical issue. I have no trouble with orgasm. I have no trouble with any of the other signs. I haven't experienced the change, whatever you are talking about. But I don't even think about sex.

So for me it is not like I'd want to just take a pill right before having sex with my husband. I want to feel it all the time. It can't -- it is not just like a physical thing, like I thought Viagra was just for erectile dysfunction where you take it if you know you are going to have sex. Maybe I'm thinking the wrong drug, I don't know. But this is something I want to experience all the time, 24/7. I want that part of my life back because just thinking about sex, not having it but even just thinking about it impacts the rest of me too. It makes me feel like a more sexual person. It makes me feel like a woman. So I would be interested in not just taking something before having intercourse or if I think I'm going to have intercourse but taking something everyday knowing that those effects are going to last me 24/7/365 you know.

DR. EGGERS: Thank you very much.

Okay. I'm going to move on. We will have time for one caller -- oh we have no callers. Okay.

Then we have more time to explore -- okay. We have one more thought. Okay. We will go there first.

MS. ROBSON: To answer your question because I've had a complete hysterectomy and had my ovaries removed I couldn't do that. I wouldn't be able to decide when I want to take something right because I'd just be going like this. I'd be roller coasting all over the place. So I need the consistency. And I think to Katherine's point is that what happened with me is I had no desire. Zero. It was gone. It was gone for a long time. And then when I finally got well it came back. And when it came back it was like -- it was pretty remarkable because I had already made the decision that I was just going to live my life that way for the rest of my life at 42 years old. And that is what happens so many times. So I am so thankful that there are options. I just wish that they were FDA approved and they were paid for by insurance. And that is one of the things that we face as women.

DR. EGGERS: So we will take two more comments. We will go to Amanda and then we will come to you.

Actually we will go to you first?

MS. MODJOROS: I wanted to echo what Katherine said. A lot of my patients don't look at this as a I feel like chicken tonight; I don't feel like chicken tonight. The benefit that Katherine wants, that a lot of my patients want, they want to feel the desire all the time. The converse is what they -- the distress that they feel. I have patients who will wake up and say okay it has been five days, it has been ten days, I have to give my husband sex tonight. They have anxiety all day long. They stress about it. They plan it out. They are like oh, my God I've got to do this and there is not going to be orgasm, there is not going to be arousal and I have to get the lubricant. All of this. And it is because it doesn't come naturally. When they were in their teenage years, when they were in their 20s it may have come naturally for them and that loss of

themselves and that constant preoccupation with what's wrong with me causes distress every day. So if they had an option to take a pill to relieve that distress or take a medication rather to relieve that distress that would be huge for them whereas I don't have many patients that would say I just want one day, I'll do something and you know see what happens. Most of them want all the time.

DR. EGGERS: Okay. We are going to go there and then we will come to you Amanda.

JENNY: I'm Jenny and I thank Veritas but I would have come anyway. I had accepted the invitation.

And I just don't see why we can't have both, the long term and the instant. You have Viagra and Cialis. So I think women should have the option as well of having it both ways.

DR. EGGERS: Thank you. And then right here. And then we have time for one more comment with Susan and then we are going to have to wrap up.

AMANDA: So I think we are talking about three separate things and I want to address the question about the intermittent use. It is my understanding from experience and from all the commercials that Viagra works on the spot as a blood flow issue. And I think that for most of us that have lack of desire and are distressed by it, it is not a blood flow issue. I mean you can just send blood down there and I'm going to all of a sudden want to have sex. It is not an issue of not being able to have sex. So what I want is to want to want it all the time to her point over her and Katherine's; I want to always desire my husband and I don't want it to be situational.

The Testosterone comment I understand that for some women it works but I think she said it perfectly when it is designed for men and so it is going to vary between women to women and that is a very valid reason why on the packet insert there are strong labels about men using Testosterone staying away from their wife or their spouse for several hours because of the transfer

and the side effects that it can cause. I actually had some of the side effects.

The goal for me is to still to have desire for Ben all the time and for it to not cause distress and to just get that desire back and the measuring a satisfying event it goes back to what I said earlier, women don't forget a sexually satisfying event. So I don't need to record that in a diary. I am going to remember that for weeks to come.

DR. EGGERS: We are going to go with Karen and then we are going to have to wrap up our -- or Susan, I am sorry Susan. And then we are going to have to wrap up the discussion.

SUSAN: I just wanted to say that as I am sitting here listening to this I feel distressed. I feel distressed that we are looking for a drug to basically achieve a perfect sex life. You know when I hear 365 days a week I think that is a lofty goal and I was just thinking that we are talking about distress and I just had to say that I feel distressed that we are looking

for perfection when it comes to sex.

DR. EGGERS: Thank you very much Susan.

With that -- well, okay, we are going to go with two more comments and we are going to go with the woman in the orange who has had her hand up patiently. And then we will come to you.

UNIDENTIFIED PERSON: Hi. I think if you are talking about something a woman could take instantaneously then you are really saying she is only responsive sexual person versus having a subjective sexual desire. And I think that -- I am a sex therapist and I feel like I have had a lot of success treating women without medication but I am here today because I believe that it also gives women a choice. I think that yes, they can work up to it, they can have good erotic stimulation, they can have even a good experience but having the choice to have desire coming into that experience is really erotic and wonderful.

DR. EGGERS: Thank you.

Okay. So briefly your comment?

MARTA: My name is Marta and I'm here

representing an organization Red Hot Mamas which is an educational company for menopausal women. And one of the things I'd like to touch on is a lot of the women that write in on the forum talk about it takes years for them to develop to the point where they are actually able to view it as a problem and to actually seek help. And how many doctors they've gone to that have said there are no options for you. I can't help you. And they are worried about their relationships. They are having a hard time with menopause anyway but they have no libido and there is no outlet, nowhere for them to go. And it is not something you can talk about with your neighbor. So it is a very, very big problem and we need a lot of choices just like men have. And that way women can actually move their lives along. And it is a big deal for marriages and relationships. So I just wanted to point that out there are a lot of women talking about it.

DR. EGGERS: Thank you. This has been a very rich discussion filled with many topics that

we could spend days covering and you spend so much of your time thinking about.

So again I am going to reiterate we want to hear from you. We only had this amount of time today to do so. But the Docket is available. We do look at all the comments that come in. So please expand upon the thoughts or thing that you want to expand upon that you heard today, please do so.

This portion of our discussion is now closing. Again we thank you so much for sharing your very personal experiences and the courage it takes to come up here and do so. So another round of applause from everyone.

[Applause.]

DR. EGGERS: Another reminder for the evaluation forms they are at the registration table or will be floating around. So please fill those out.

And now I will turn it over to Pujita who is going to do the open public comment. So thank you very much.

[Applause]

MS. VAIDYA: Hello everyone. I'd like to thank you all for coming here today. And we are now moving into the open public comments session. And for those of you who are not aware the purpose of this session is to allow an opportunity for those who have not had a chance to speak on issues that are not related to our two main discussion topics. This is an opportunity for folks who are not patients or patient representatives to comment.

Please keep in mind that we will not be responding to your comments but they will be transcribed and be part of the public record.

For the sake of transparency we request that you disclose if you are affiliated with an organization that has an interest in drug development, in FSD, or if your travel here today has been funded by an organization, or if you have significant financial interest in any pharmaceutical companies. If you do not have any such interest, you may state that for the record

as well.

So we have collected sign up before the meeting. We have 15 people signed up and about 30 minutes for this session. So please be respectful to your other colleagues here and other patients and stick to the two minute limit that we have. We have a timer up front. I have it here. And when the light turns from green to red over here that means your time has ended and I will then ask the next speaker to come to the mic.

So I'll run through the order of the speakers and I apologize if I mispronounce your name.

So first we will have Leonore Tiefer, Alessandra Hirsch, Thea Cacchioni, Sidney Wolfe, Rebecca Holliman, Judy Segal, Ashland Gena, Kimberly, Sally Greenberg, Deborah Arrindell, Susan Scanlon, Beth, sorry. I'll get back to you, sorry, Sue Goldstein, Amanda, and then Michelle Robson.

So first could I have Leonore Tiefer to the mic please? So we have two mics set up, one

to the right and one to the left. So if Leonore could come to one of them and then I'll have Alessandra Hirsch at the other one ready for the next one.

DR. TIEFER: Hi. So I'm Leonore Tiefer. I am a New York Psychologist and the founder of the New View Campaign which is a campaign to challenge medicalization. I've thrown my remarks out 12 times. I feel like this has been a surreal meeting. It's -- we are talking at cross purposes with each other. And it was very distressing that we sort of start off this meeting by saying we are committed to developing a drug when, in fact, we can't even agree on what it is for. And we have an over representation of people who are taking drugs paid by drug companies to come and talk about them.

This is not the way to do science. There is nothing representative about what is going on here. We have a huge literature on psycho-educational, psycho-therapeutic, self learning, spiritual methods to understand

sexuality. And what I hear here today is there are people who believe deeply in normality. And they had it and they've lost it and they want to go back to it. And then there is the rest of us who believe that the whole thing is a process going forward. It is not a medical model. There is no normal that you lost and you are going back to. It is the wrong way to look at it.

We need move conversation. We don't need to move into drug trials.

[Applause.]

MS. VAIDYA: Thank you.

Next Alessandria and then could I get Thea to the mic, please. Thank you.

You have to turn it on.

MS. HIRSCH: Hello. My name is Alessandra Hirsch. I have a master's degree in physiology from Georgetown University Medical Center. And I currently work as the project manager for PharmedOut which is a program that educates health care professionals on pharmaceutical marketing practices and encourages

evidence based prescribing.

I speak to you today as a young woman who is concerned about the implications of treating female sexual dysfunction with Flibanserin and other drugs. And I speak only for myself.

When I mentioned to a male friend the idea that the FDA is sexist because it has not approved a female sexuality drug whereas it has approved a bevy of similar drugs for men he laughed at me and said if a good female sex drug had been invented and the FDA were truly sexist it would have been pushed faster than aspirin. Perhaps my friend has a point. What could be more keen to the male interest than a drug that encourages women to have more sex?

Let's take that implication a little bit further. I imagine myself in bed with my partner. He initiates a sexual encounter which I rebuff. Today because I have a kind and attentive partner my refusal would not equal rejection but merely a reflection on my mood that day. We would go to

sleep.

Years from now with a drug that treats FSIAD on the market he might say to me it is okay that you are not in the mood, why don't you just take your pill for that? What if I still refuse? Do I lose the right to say no because there is a pill to fix me?

The scenario that I described seems to me like a very possible outcome in addition to the already exhausting list of micro aggressions that affect women daily.

Here are some things that have helped me with period of low libido. My boyfriend, switching boyfriends, chocolate, coffee, certain episodes of Grey's Anatomy, pornography, upgrading my vibrator, the phrase a little to the left, the phrase not so hard, the phrase I love you, reading Fifty Shades of Grey, removable shower head, having tips from my girlfriends, having backrubs, back scratches, a good night sleep and absence of judgment from my boyfriend and an absence of judgment from my friends, a defiance of judgment

from society and an acceptance of myself and the libido I came with.

MS. VAIDYA: Excuse me, Alessandria, your two minutes is up.

MS. HIRSCH: That is okay. Thank you.

[Applause.]

MS. VAIDYA: Can I please have Sidney Wolfe to the stand to the right please. Thank you.

DR. CACCHIONI: Hi. My name is Thea Cacchioni. I have a Ph.D. in the psychology of sexuality from the University of Warwick, U.K. and I'm a professor at the University of Victoria, British Columbia.

I would like to personally thank the FDA for at this point not approving a drug that is unsafe or ineffective. I think there have been enough drugs in the history of women's health as we heard from Karen's comments today that have been approved without enough research.

A subtext of the discussion today is that many women's sexual difficulties are the side

effects of drugs that have been approved for the treatment of other conditions. And yet we've also heard a lot about the off-label use of drugs which have not been approved for this reason and that concerns me very much as well as the various ways that they are being used out there in the world.

I'd like to just express disappointment to that. This is a patient centered hearing and yet it seems as though it has been mainly people who have been sponsored by industry who have been able to afford to attend. I don't think it is truly representative; not to take away from your experiences.

So just to conclude I would like to say it seems as though the line between industry and patient perspectives is very thin.

[Applause.]

MS. VAIDYA: Thank you.

Sidney Wolfe and then could I have Rebecca Holliman to the mic on the left please. Thank you.

MR. WOLFE: Sid Wolfe, the Health

Researchers Group. Don't have any financial conflicts of interest. Just one quick comment before the other three quick comments.

One, no drugs have been approved for man or women for this purpose. The FDA took a strong position at a hearing last month in September that use of Testosterone for a whole variety of things including pre-sexual desire there is no evidence for it. I got involved in these issues about ten years about when I testified along with Dr. Tiefer at a hearing where they were considering the approval of Testosterone patch for women. The physician who reviewed the drug said "the clinical significance of the increase with active treatment yielding on average of only five to six points more than placebo on a score of 100 for sexual desire is unknown".

More recently in 2010 another drug Flibanserin which has been mentioned several times was also turned down and one of the reasons it was turned down again was that the placebo response rate was really quite high. And in an interesting

article by someone who has been here and has spoken, Dr. Kingsberg, after this hearing and after the drug was turned down she commented on the placebo effect. They can be explained by other more psychological factors, for example, women enrolled in these trials that desire to improve their sex lives and take an active role in seeking help. Additionally expectancies for enhanced sexual desire would increase a woman's perception of having desire. Two frequent diary entries which she opposed and which some people today -- were the sum and substance of at least one of the reasons why the placebo worked.

And finally before the microphone gets turned off it is a very complicated issue. Everyone has agreed that it is and since we are only about 30 miles from Baltimore where H.L. Makin was. The quote with Makin "for every complicated problem there is a simple solution which is usually wrong".

Thank you.

[Applause.]

MS. VAIDYA: Thank you.

Next we have Rebecca. And then could I get Judy Segal to the mic as well for after. Okay. Go ahead Rebecca.

MS. HOLLIMAN: Hi my name is Rebecca Holliman. I'm a graduate student at Georgetown University. And I work as volunteer staff for PharmedOut which is a Georgetown project that aims to encourage evidence based prescribing. I have no financial conflicts of interest.

I worry about the potential harm to women if we leave this issue solely in the hands of the medical community. Sex is complicated. Biological function cannot be isolated from physiological, psychological and social factors. It would be a disservice to women to take this approach.

The doctor's office can be an intimidating place for women to address concerns about their sexuality. Women are left vulnerable to messages designed to push a profit instead of to educate.

Pills have a higher profit margin than education but opting for the quick fix may cause more harm than good.

In an article written by Grant Stoddard he described his experience with having sex on Viagra. In it he made the comment penises are often referred to as tools and that is exactly what mine felt like a wood-like dodonic (ph) prosthesis that was being ridden with little emotional or physical input from me. The experience was strangely feminizing. For the first time I was a passive partner during sex without necessarily being turned on or even having my head in the game.

Maybe we have already done men a disservice in focusing on medication to fix the machinery of sex at the same time spreading the message that the body is the only part of them that matters. The emphasis on a medical fix is likely to prove more damaging than helpful to women in the long run. Medical technology is too easily manipulated a device. I can imagine the

commercials already. He made you dinner, he bought you roses, don't you want to be able to respond.

A pill or device in a market with inadequate infrastructure to educate women about the non-medical components of arousal is dangerously open to abuse. Once again women will become little more than the functions of their bodies.

Thank you.

[Applause.]

MS. VAIDYA: Thank you.

And next we have Judy. And then could I get Alska (ph) Ashley to the mic, please.

DR. SEGAL: Hi, my name is Judy Segal. As I mentioned before I'm funded by the Social Science Humanities Research Counsel. I'm a professor at the University of British Columbia and my area of research is discourse language and persuasion in health and medicine.

And so I do want to make another comment about some of the language I've heard today.

One of the words that has been missing has come up from time to time but it hasn't been at the center of anything in terms of goals of treatment end points is the word pleasure. It seems to me that a lot of what I've heard about is well interest, arousal, orgasm, husbands, guilt, anxiety, wanting to be free of those but I haven't heard a lot about pleasure. And it seems to me that if we don't talk about sexual pleasure in women as an end point of treatment if there is going to be some kind of treatment then that is say sexist, anti-feminist, in a way that I think not approving drugs that haven't been shown to be safe and effective isn't sexist and anti-feminist.

Thank you.

[Applause.]

MS. VAIDYA: Thank you Judy.

Next we have Ashland and can I also get Kimberly to the mic.

MS. JERVIS: Hi. My name is Coco Jervis. I will be speaking on behalf of Ashland. I'm the

program director at the National Women's Health Network. The Network talks to patients and other concerned about sexual problems and/or women's health voice information service. The Women's Health Information Service is supported by our members. We do not take any financial contributions from drug companies, medical device manufacturers, insurance companies or any other interest that have a financial stake in the women's health decision making.

The Women's Health Voice was launched in 1978 and has operated continuously since then. Women routinely contact us with questions about sexual problems. And the questions that they ask us are is this normal? Are my sexual problems caused by something a medical professional did? Does the medical profession have anything to offer me? Does what is being offered work? And what are the risks and side effects of what is being offered? And are there alternatives?

What we have found when talking to women with concerns about sexual problems is that good

answers do not exist to any of the questions women ask us. And on behalf of hundreds of women who have brought these questions to us via the Women's Health

Voice we want the FDA to know the following: women want more information about what is normal but not just what is hetero-normative. They want to know about natural history studies of changes in sexuality including desire, arousal, and a response with age and reproductive events. Women want more information that is currently available about the effectiveness of medical treatments, procedures and medications on the desire and arousal and satisfaction.

Then of course some of them want to know what medical treatments are available. They want to know if treatments they've heard about are legitimate and stringently evaluated by the FDA. They want to know if medical treatments actually work and how well. They want information on about what exactly effective means.

Women who contact us with questions

about sexual problems want reliable information about the risks of side effects associated with medical treatments.

[Applause.]

MS. VAIDYA: Thank you.

Next we have Kimberly and can I get Sally on the mic as well. Okay.

KMBERLY: Hi. My name is Kim and I am just representing myself. I view myself as a potential patient as a pre-menopausal woman who has young children and as a doctoral student. I understand fatigue and I understand how that affects my own desire.

But I am most concerned that any medication that is on the market be both safe and effective for its intended use.

And I just wanted to mention how greatly I appreciate that the FDA is dedicated to both safety and true efficacy.

Thank you.

[Applause.]

MS. VAIDYA: Thank you.

So next we have Sally. And then could I also get Deborah.

MS. GREENBERG: Good afternoon. My name is Sally Greenberg. I'm the Executive Director of the National Consumers League. We are the oldest consumer organization in the U.S. founded in 1899 by pioneering women during the progressive era who focused much of their work on health care and work place protections for women and children. And they fought passionately for women's equality and fair treatment.

More recently NCL has been a champion for the safe use of medications and work closely with the FDA on better medication adherence through our Script Your Future Campaign.

I'm here today because when it comes to sexual dysfunction treatments and I am going to talk really fast it is clear that we have a gross gender imbalance in products approved for men versus women. With 26 new drugs either approved or marketed for different aspects of male sexual dysfunction including erectile dysfunction,

Peyronie's disease, loss of libido due to hypergonadism.

There is nothing so far for women in the most common form of sexual dysfunction, HSDD. And we have to ask the question why? Viagra was approved for erectile dysfunction 16 years ago. It was fast- tracked at the FDA and review in one six month cycle despite a long list of adverse reactions including very serious cardiovascular effects especially if it is co-administered with other commonly used drugs.

16 years later despite worthy efforts women still do not have an FDA approved safe and effective treatment for HSDD.

This is what women end up doing is they go to the Internet and they buy I have 51 examples here of stuff on the Internet that claims to provide increased libido for women. These treatments are proven neither safe nor effective and because the FDA has dragged its feet and failed to act and address this gender imbalance we have women going and getting products that could

hurt them and waste their money.

So if we sound angry; if I sound angry, I am and I think -- congratulate the FDA for doing this workshop here today but we need to move beyond this -- I'm cut off so thank you for your time, you get the picture.

[Applause.]

MS. VAIDYA: Thank you Sally.

We have Deborah ready to speak and then can I get Susan right after her.

MS. ARRINDELL: Good afternoon. I'm Deborah Arrindell with the American Sexual Health Association. Our organization was established in 1914 when women were largely considered vixens, vectors or infections, and maybe vamps.

It is wonderful that we've come to the point where we can begin to talk about women having healthy sexual lives. Women have right perhaps to desire, arousal, even pleasure. So we really appreciate that the FDA has today given organizations like mine and people like me an opportunity to hear from patients which I have

things I have only read about. And what I've heard is despair, anxiety, loss of confidence, loss of self-worth, troubled relationships and families in crises. And sexual health, we believe, is a basic human right.

What we've heard is that women will try everything including "some things I don't even remember the names of". And indeed I do believe for some women chocolate, strawberries, and certain episodes of Grey's Anatomy can make a difference. But for many other women that is simply not the case.

We heard that for some woman a month in the Caribbean would not do the trick. Not being able to have sexual desire will only add to anxiety there.

So I believe that sexual health is a basic human right and those are the women for whom we ask the FDA to provide some options. We don't want a magic pill. We want an opportunity for those women and their providers to together figure out what is right for them and what might work.

I believe that deeply buried in the Constitution there must be a basic right to healthy sexuality. I am going to go with the Pursuit of Happiness.

Thank you.

[Applause.]

MS. VAIDYA: Thank you very much.

Next we have Susan. And after that we will have Beth.

MS. SCANLAN: Hi. Thank you for letting me speak. I am Susan Scanlan. I am Chair Emeritus of the National Council of Women's Organizations, a coalition of 240 progressive women's groups representing 12 million American women. I am also Chair of Even the Score a coalition of patients, providers, advocates and practitioners who have come together to address the gender disparity in treatments for male versus female sexual dysfunction.

There are 26 drugs approved for men and zero for women. Up to one in ten women, American women, suffer from FSIAD. That represents as many

as 16 million women with no answer to this devastating condition.

How pervasive is the problem? 75 percent of women patients here today are not from the Washington, D.C. area. They are from all over the country. And they need and deserve our help.

And let me salute the women who came here and husbands who spoke; so courageous.

We support medical treatment for FSIAD. We are tired of hearing that female sexual health is complex as if there would be no answer if we didn't study it. Make no mistake men are equally complex and there has been no shortage of medications to address their sexual dysfunction.

In 1960 the birth control pill precipitated a societal shift to recognize women's rights as reproductive beings.

In 2014 let's shift to recognize women's rights as sexual beings.

Thank you very much.

[Applause.]

MS. VAIDYA: Thank you.

Next we have Beth and then Sue.

MS. BATTAGLINO: Hi. I'm Beth Battaglino. I'm CEO of HealthyWomen.org, the leading not for profit consumer women's health organization who represents more than five million women annually that visit our Website. And I want to share with you that the top three topics that trend the most women's sexual health continues to be in the top three. So we know that women are seeking information and want information and feel that they need to go to a lot of Websites to find that information because it is an embarrassing topic for so many.

I also want to share that we recently did a survey of over 1,000 women and 81 percent of the women that took the survey said that their sexual relationships or lack of sexual relationships is very distressful in their relationship and more than 53 percent of these women said that they've been living with this for more than a year.

So it is time that we do something. And

they have more options.

I also want to share that Healthy Women will continue to provide women with credible medically researched and vetted information and that is how we have remained in business for over 26 years.

And I want to thank the FDA for commencing this panel. I think it is important but more importantly I really want to thank the real women and your real voices how powerful and so nice to have your spouses here. So thank you.

[Applause.]

MS. VAIDYA: Thank you Beth.

Next we have Sue and then Amanda.

MS. GOLDSTEIN: I am Sue Goldstein. I am a sexuality educator and a clinical researcher. And I'm here representing the everyday patient rather than the large societies. I've interviewed a great number of patients in my lifetime, first to write a book, and then working with them for clinical research.

And women are angry. And I'm here to

thank the FDA for bringing up this topic for us being to talk about it. As a sexuality educator one of the messages I would like to say is as long as we hide behind walls and we whisper about what we do; how can we expect everybody out in the community to be comfortable talking about sexual health.

Women are afraid to talk to their physicians about their sexual health problems. And if they do, what they are told go get a glass of wine, go away for the weekend. And they know that is not the solution. Yes, you can say sex is complicated. The fact is sex is multi-factorial. It is multi-factorial for women. It is multi-factorial for men. And what we do is we do our best. And we have been able to come up with solutions for men and I'm hoping after this forum the FDA will work with companies so we have solutions for women.

But there area women out there who are angry because there is nothing for them and they are being told you can't have a choice. All we are

asking is we're Americans, we have a choice whether we can choose abortion or not, we don't have to go to the back rooms and get coat hangers into our cervices to abort. We want a choice that if we want to have a biologic therapy in addition to or instead of physical therapy, sex therapy, we need a choice. All we are asking for is a choice. Nobody is telling anybody else they need to take a medication. We are just asking to make those options available.

Thank you.

[Applause.]

MS. VAIDYA: Thank you Sue.

Next we have Amanda and then finally Michelle Robson.

AMANDA: Thank you. I have a very healthy marriage and we have a very open line of communication. We are not here looking for perfection and Ben is not here to expect me to meet his demands. Instead we are looking for restoration of my sexual desire.

As we age we lose things. When we lose

the ability to sleep many of us take a sleep FDA approved medication. Some choose not to treat. When we lose the ability to handle stress some of choose an anxiety medicine that the FDA has approved. Others choose not to. So when we lose our desire to have sex with our husbands do we not have an FDA approved option to choose from. I recognize and respect that some choose not to do that and that is their choice. But as an educated professional woman who understands the risks and benefits associated with taking prescription medicine I would appreciate having the chance to have an FDA approved option to choose from and to allow me the opportunity to work with my physician in finding a solution to this problem.

I've heard it said a lot today that it is complex. It is really not. It is really not any more complicated than anything else that we lose.

BEN: And I just want to say that men have many options when it comes to sexual dysfunction. Women deserve to have some options

too.

Thank you.

[Applause.]

MS. VAIDYA: Thank you.

And finally we have Michelle Robson.

MS. ROBSON: Thank you for the opportunity to speak today before the FDA. I have no affiliation which I've already said and I have no financial gain. My name is Michelle King Robson. And I am the founder of EmpowHER.com. We have over three and one half million women coming to our site every single month. What do we see? The top five is sexual health and relationships every single day because we track this on a daily basis.

I to suffered from sexual dysfunction. It is one of the reasons why I started the company. I see how women are silently suffering because that is what women do. We don't have options and choices. We need options and choices today.

Without the option and choice that I had

to go to compounding and to have an FDA approved patch I would not be standing in this room. I would not have created this company. I would not be helping millions of women around the world who are dealing with health issues.

Women's health is underserved. It is very clear that it is very underserved. And it has got to change. We are no longer viewed as just vehicles. We are bearing children and we are contributing to society and paying taxes as well.

When I spoke to you in 2010 my story and the data was there and the data hasn't changed and it is now 2014.

Generations of women have suffered in silence for far too long, far too long. And it is time for the FDA to act. Please act.

Treatments and open doors for research and find more and better solutions and to no longer say no. We deserve no less. Just say yes.

[Applause.]

MS. VAIDYA: Thank you.

That brings our session to the end. And I would like to call Dr. Sandra Kweder to the stand for our closing.

DR. KWEDER: Well, good afternoon, everyone. And I recognize that we are ten minutes before you opportunity to stand up and stretch. So I'm going to try and summarize what we heard today. And I hope you can bear with me because I am looking at my little laptop screen.

But I did try to divide my comments into a couple of areas. One of which is separated first by the two panels and also acknowledging some of the general comments that were made.

First I want to thank you for all my colleagues here for being here and spending the day in a room that is sometimes a little dark and seats that are often a little uncomfortable. And in particular for expressing yourselves and a willingness to listen if you didn't express yourself to a discussion about a topic that is sometimes a little uncomfortable. And if you have any doubt about that I ask you to think back to

the first panel that got up when Sara got up and tried to generate some discussion. I could see people shifting in their seats. There was a little silence and people are thinking oh my gosh how are we going to fill this afternoon. But quickly you arose to the occasion and I am really glad that you did.

I found it very informative and I think I speak for my colleagues in that manner as well.

We are not here to solve all the world's problems. That is way beyond any of our pay grades. But we are here to listen and try and respond professionally and thoughtfully to concerns raised by patients who have conditions or concerns that you think that we need to hear about. And you certainly outdid yourselves today in expressing that.

I do want to acknowledge and we heard this throughout the comments peppered during the day and at the end in the open public hearing that -- I want to acknowledge that there is a breadth of perspective on the issues that we discussed

today. I would be gravely disappointed if there were not a breadth of perspective. And any time we at the agency tackle something that is difficult there is a wide breadth of perspective and people feel very passionately along that full spectrum. That is just fine.

So I will acknowledge that there remains some who are concerned that we need more attention to the etiologies and I use plural and physiology of female sexual disorder conditions that have been the focus of today's discussion particularly they expressed concern about the need to consider the natural variation in sexual desire from one person to the next or over the course of any individual's lifetime and life experiences.

Another concern that was expressed was that we always take care not to allow undue influence from the pharmaceutical industry in any discussions of any particular medical condition.

And other speakers expressed concern that not enough attention has been paid to addressing treatments for women who are

experiencing this condition that we discussed today and there is actually probably a spectrum of conditions based on the kinds of things people raised their hands about in describing their own circumstances.

But acknowledging all that I'd like to try and summarize what we heard from Panel 1 that was so eloquently expressed by the panel members. What was most striking to me was how similar the experiences described by the four panelists seemed to be to those who subsequently expressed themselves in the discussion portion following that panel. I would just recount that 75 percent of you who voted cited no or reduced excitement or pleasure during sexual activity. 75 percent expressed no or reduced non genital sensation during sexual activity. And a large number of you as well particularly made a point to express that your major issue of concern is a lack of any desire to even contemplate sexual activity in the first place.

And I would say that was one of the most

important messages for us today was that this complete lack of interest in sexual activity seems to be a really predominant feature that many of you shared often to the point of working hard in your life to avoid any experience in life or circumstance in your day-to-day existence that might result in pressure to engage in sexual activity.

There was an expression by many of having great difficulty in becoming sexually aroused at all with some noting that they can't reach orgasm; although most expressed the difficulty in becoming aroused at all as more important than any orgasmia.

Many of you expressed a point in time in your life when you recognized that suddenly something changed. For some people it was the birth of a child, for some people it was surgical intervention. There were a variety of things expressed. But you referred to what was -- had always been for most of your life normal very suddenly became different. Although others of you

expressed that the onset of this was different. And some who spoke expressed the importance of factoring in age, the variation in that according to a particular age or period of physiologic differences in a woman's life.

One of the things that I heard was that interest is different from arousal. Interest is different from the physiologic process of arousal itself. And arousal may often be generated by interest or physical stimulation but many women experience difficulty in both of those spheres. There is like a Venn diagram where they overlap but they are different.

With regard to signs and symptoms it was interesting when Sara brought up the issue with regard to signs and symptoms this discussion of what constitutes a satisfying sexual experience. And some of you expressed that a satisfying sexual experience is not something that is easy to measure. It means different things to different people. But you all raised your hands to indicate that having satisfying sex is different but it is

highly different depending on the individual.

Overall I think there seemed to be a convergence on satisfaction being related to some sense of emotional positivity and sense of self worth. To me this is an important component. I think we are going to hear more about that tomorrow when we talk about the aspect of being able to measure sexual satisfaction in clinical studies of new drugs. It is something that is often prominent in the scoring system used. So understanding what is behind those is really, really important.

In terms of the effect of the disorder or variations in the disorder on people's lives and functionings all who spoke and this was quite striking indicated what a profound affect this has had on your lives beginning with stressing the effect on your sense of self worth but in particular your relationships. Not and most prominently your relationship with your spouse or significant other or sexual partner but also how that affect impacted you beyond just that one-on-

one relationship. It affected oftentimes your family lives, your relationships with your family, how you felt about yourself in your ability to do other things in your life.

Some described a cycle of anxiety and disappointment associated with coping with the condition. And it was noted and duly noted on our part that having some input as we think about measures to assess this condition getting input from partners of women with this disorder may be important in our understanding its impact on people's lives.

So to move on to Panel 2 and trying to grasp current approaches to treatment, current treatments and how well they worked I did note among the four panelists there was one panelist who focused most particularly on the facilitated work on relationships and developing a sense of really understanding intimacy itself as part of addressing this disorder. And interestingly it was about one in four and also about 25 percent of the people in the room who had done some sort of work

like that in seeking to address this disorder. So it seems like the panel was quite representative of the people in the room.

The types of things that were mentioned included Estrogen treatments, various forms of Testosterone, a lot of emphasis and discussion on Testosterone. And you really reflected a gamut of experience from topical, injected or pellets. And what was also striking was there was a great variation in people's experiences and success in treatment with Testosterone which does suggest that there may be different underlying etiologies of this condition that may respond differently to different hormonal interventions.

Estrogens I think we can say that the responses were similarly varied. Several of you mentioned systemic use, noticing improvement in symptoms including more widespread affects that go beyond just sexual function but to other aspects of functioning in day-to-day life particularly those women who had experienced surgical menopause or menopause again going back to the spectrum of

affects, impacts that different stages in life can have on sexual functioning.

Interesting that PDE5 inhibitors, the Viagras, the Sildenafil, Cialis and the other things, some have tried them. Those who mentioned them seemed to be not particularly enamored with their effectiveness.

And several of you mentioned trying a variety of over-the-counter products to try and address your concerns.

Several in the room have participated in clinical trials for Flibanserin and those who did mentioned that they had participated indicated that they had had positive effects from that drug on sexual desire.

The side effects that were mentioned were not surprising, in particular I would say the most prominent one was undesired hair growth with Testosterone was the one that was mentioned most often and a variety of other things but didn't seem to have any patterns.

As far as an ideal treatment I thought

that discussion was interesting. Overall a subjective -- what most people seemed to desire most was something that would bring them back to what they saw as having a healthy sexual life and desire to engage in sexual activity. It seems to be the most elusive aspect of successful treatment from what I heard today and probably one that needs the most focus in developing therapies.

Favor was expressed by some for treatments that can be managed on an as needed basis. But it was also important to some of you that this isn't something that comes and goes, this sense of self worth that one has from being able to have a sense of being a sexual being isn't something that comes and goes, it is kind of a continuum or a continuous desire to feel what one perceives as normal.

So I'm not sure there is one ideal. I don't think I came away with a sense that there is one ideal but that there is probably breadth in perspective on this issue. And I think as we proceed and encourage companies to proceed with

considering therapies in this area and using measure and considering clinical trials for any products that are developed in this field; those are factors that we all collectively in here at FDA and academia where people, and in clinical medicine and in the pharmaceutical industry are going to have to probe these issue a little bit further.

So I couldn't capture absolutely everything that you expressed. I would have been up here all afternoon because that is how long it took to express these things. But I do hope that I've touched on some of the major themes.

I think -- I hope that most of you are planning on being here tomorrow because the discussion will be expanded from this to taking what was said today to thinking about how to measure these things; how to take them into consideration in clinical studies; how to develop a study end point and measures of this of these factors that are so important to you as patients so that in any clinical trial we can do you

justice and really assess therapies and whether they really do achieve the things that you find most important in meeting your needs.

So again thank you for your attention. Thank you for your serious consideration of the plethora of issues that we have before us.

And I hope many of you will be joining us tomorrow.

Thanks very much.

[Applause.]

(WHEREUPON, the public meeting concluded.)

CERTIFICATE OF NOTARY PUBLIC

I, MICHAEL FARKAS, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was recorded by me and thereafter reduced to typewriting under my direction; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

MICHAEL FARKAS
Notary Public in and
for the State of Maryland

My commission expires: 6/27/2018

Notary Registration No.: 256324

CERTIFICATE OF TRANSCRIPTION

I, CHERYL LaSELLE, hereby certify that I am not the Court Reporter who reported the following proceeding and that I have typed the transcript of this proceeding using the Court Reporter's notes and recordings. The foregoing/attached transcript is a true, correct, and complete transcription of said proceeding.

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